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Food·Drug·Cosmetic Law Journal

OCTOBER · 1956

A Report from England . . . . . .
CHARLES A. ADAMS, C. B. E.

New Measures of Control of the Traffic in Narcotic Drugs and Marijuana . .
ALFRED L. TENNYSON

Food-Additives Amendment of the Federal Food, Drug, and Cosmetic Act
. . . . . GLENN G. PAXTON

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A COMMERCE CLEARING HOUSE PUBLICATION

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The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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About the Authors

Most of the papers in this October JOURNAL were delivered at the annual meeting of the Division of Food, Drug and Cosmetic Law of the Section of Corporation, Banking and Business Law, American Bar Association, at Dallas, Texas, on August 28. Two other papers, both by Canadian authors, round out the issue.

Charles A. Adams, C. B. E., is director emeritus of the food standards and labeling division in the United Kingdom Ministry of Food. He had been a career employee with the British Government since his graduation from London University in 1911.

Mr. Adams received his early education in his home town of Swindon, Wiltshire, England, and went on to the University College of Wales, at Aberystwyth, in 1908. He continued with chemistry work at London University.

Called to the bar (Honourable Society of the Middle Temple) in 1925, Mr. Adams was later made a fellow of the Royal Institute of Chemistry. He is a past vice president of the Society of Public Analysts. Mr. Adams was appointed a public member of the Lawyers Advisory Committee of The Food Law Institute in 1951.

Alfred L. Tennyson, chief counsel in the Bureau of Narcotics of the United States Treasury Department, was graduated from Georgetown University School of Law in 1922, and is a member of the District of Columbia and the United States Supreme Court bars. A specialist in legal work connected with narcotic-law enforcement, he has held his present position for 22 years.

Mr. Tennyson has acted as adviser to the Commissioner of Narcotics at sessions of the United Nations Commission on Narcotic Drugs. These sessions were devoted to drafting of proposed international agreements on control of traffic in narcotic drugs and marijuana.

As a member of the law firm of Campbell, Miller, Carroll & Paxton, **Glenn G. Paxton** is engaged in general practice in Chicago. He is general counsel for the Millers' National Federation, the trade association for the flour-milling industry. Mr. Paxton represented various food industries in the hearings conducted, early in 1956, by the Committee on Interstate and Foreign Commerce of the House of Representatives on various bills to amend the Federal Food, Drug, and Cosmetic Act to regulate the use of additives in foods.

Elwyn L. Cady, Jr., is currently the assistant director of the Law-Science Institute, sponsored by the schools of law and medicine of the University of Texas, Austin. He also serves as visiting associate professor of law there. His actual practice is as a medicolegal consultant from his Kansas City, Missouri offices. He holds degrees from Tulane University College of Law (Ll. B., 1951) and from the University of Missouri School of Medicine (B. S., 1955).

Born in England in 1896, **H. A. Watson** went to Canada in 1911. After four years of work in the laboratories of the Canadian Pacific Railway and the Purity Flour Mills Company, at Winnipeg, he went overseas during World War I. On returning in 1919, Mr. Watson joined the staff of the grain research laboratory of the board of grain commissioners. After about a year, he entered a science course at the University of Manitoba, graduating with a B. S. degree and a gold medal in 1924. During his course, Mr. Watson engaged in tutorial work in chemistry on the university staff and took summer work with the grain research laboratory.

(Continued on page 556)

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Food·Drug·Cosmetic Law Journal

A Report from England

By CHARLES A. ADAMS, C. B. E.

This Paper Was Read at the Annual Meeting, Division of Food, Drug and Cosmetic Law of the American Bar Association's Section of Corporation, Banking and Business Law, at Southern Methodist University, Dallas, August 28

IT IS exactly two years since my last report from the United Kingdom was presented, and obviously the first thing to tell you is that the legislation which was then before Parliament has now been enacted. It is possible, therefore, to give you an outline of the new legislation now in force, free from the "ifs" and "buts" which must apply to the most intelligent anticipation. Except insofar as it may be affected in its application by the issue of regulations, this legislation seems likely to remain in force for many years to come.

In my last report,[1] attention was called to the food and drugs amendment bill then under discussion in the legislature. It was explained that the major purpose of the bill was to give a place in our permanent legislation to such changes in food and drugs law as had been introduced of necessity during the war and had proved worthy of retention. The Food and Drugs Amendment Act, 1954, received the royal assent on November 25, 1954.

It may come as a surprise to hear that this act has already been superseded by the Food and Drugs Act, 1955 (4 Eliz. 2. Ch. 16), and

[1] 9 Food Drug Cosmetic Law Journal 573 (October, 1954).

Mr. Adams, the Director Emeritus, Food Standards and Labelling Division, United Kingdom Ministry of Food, Is a Member of This *Journal's* Editorial Advisory Board

that the Food and Drugs (Scotland) Act, 1956 (4 Eliz. 2. Ch. 30) applies similar provisions in Scotland. This being the case, the 1955 act alone will be referred to in what follows. There is nothing very mysterious about the short life of the amendment act, however. The changes in the law included in it were debated by both houses of Parliament, and, though it brought this branch of our legislation up to date, it was an inconvenient measure to administer, owing to its dependence on the provisions of earlier statutes. Legislation by reference has little to commend it, so the government proceeded immediately to frame the two measures applying to England and Wales, in the one case, and to Scotland, in the other. The preamble to the former describes it as "an Act to consolidate the Food and Drugs Act, 1938, the Food and Drugs (Milk, Dairies and Artificial Cream) Act, 1950, and the Food and Drugs Amendment Act, 1954, together with certain other enactments. . . ." Its passage through the house called for little debate, for the work had already been done in the debates on the amendment bill. At first sight the procedure may appear cumbersome, but it was adopted to meet the convenience of the Parliamentary timetable. To clear up one other matter before proceeding, it should be stated that the milk and dairies legislation mentioned in the preamble quoted above is of local interest only, and no further reference will be made to it.

Readers of the JOURNAL will hardly need to be reminded that the basic provisions of our legislation were those contained in the Sale of Food and Drugs Act of 1875,[2] which dealt with the adulteration of food and drugs and with offenses arising from their fraudulent sale or advertisement. The first major advance from the position then estab-

[2] 5 Food Drug Cosmetic Law Journal 642 (October, 1950); 6 Food Drug Cosmetic Law Journal 247 (April, 1951).

lished came in 1907, in the Public Health (Regulations as to Food) Act, which gave power to the government to make regulations to deal with the prevention of danger to health arising from the handling and preparation of food in commercial channels. (The present regulations controlling the use of preservatives in food were made under these powers.)[3]

The Food and Drugs Act of 1938, which immediately preceded the current legislation, was a major consolidating measure, though it contained important new powers, notably those dealing with food standards, which were widely used during the war. With this in mind, it cannot be said that the 1955 Act has introduced much that is entirely new, though its provisions dealing with the composition of food have been amplified to meet some of the problems attendant upon the development of modern food technology. The Act is a long one, covering 113 pages, but a glance at its contents—which is given below only for purposes of record, will be sufficient to show that most of it is of local importance. This is as follows:

Part	*Sections*	*Subject*
1	1-27	General provisions as to food and drugs
2	28-48	Milk, dairies and cream substitutes
3	49-61	Regulation of markets
4	62-81	Slaughterhouses, cold air stores
5	82-121	Administration, enforcement, etc.
6	122-137	Miscellaneous and general

Part 1 of Main Interest Here

For the purpose of this report, attention can be restricted almost entirely to Part 1. In this, Section 1 deals with the sale and advertisement of foods rendered injurious to health by the abstraction or addition of any substance in the preparation of such food. The corresponding offense in the case of drugs is the abstraction or addition of any substance which affects injuriously the quality or potency of the drug. As regards foods, an attempt has been made to guide authorities in their determination of what constitutes injury to health in Section 1(5), thus:

> In determining . . . whether an article of food is injurious to health, regard shall be had not only to the probable effect of that article on the health of a person consuming it, but also to the probable cumulative effect of articles of substantially the same composition on the health of a person consuming such articles in ordinary quantities.

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[3] 8 Food Drug Cosmetic Law Journal 92 (February, 1953).

Section 4 preserves the power, in the interest of public health or "otherwise for the protection of the public," to make regulations as regards the composition of food and the use of any process or treatment in the preparation of food. At the same time, power is given to prohibit or regulate the sale of any substance for use in the preparation of food. Here, then, is the authority to prescribe food standards and to control the use of chemical additives in food. Further, attention is called to the undesirability of adding substances of no nutritional value to food and, clearly, this practice is likely to receive official discouragement.

Confidential Information on Ingredients and Additives

As a corollary it was recognized that lack of information about the new ingredients and chemical additives going into food manufacture would hamper the administration of the above section. Section 5, therefore, gives power to make orders requiring persons concerned with the production or use of specified substances to provide in confidence information about the composition and use of any such substance, including particulars of the chemical formula, details of the manner of use, and particulars of investigations as to the effect of the substance on persons consuming it, including its cumulative effect. It is to be assumed that, in the event of such information's being regarded as entailing a health hazard to the consumer, the powers of prohibition in Section 4 would be invoked. It is difficult to foresee how often these powers will be used, or what effect they are likely to have on the growth of the use of chemical additives. You are all well aware of the proposals which have been made in the United States in relation to these problems and, though you may think that the United Kingdom powers have hardly enough bite in them, it can at least be said that a step forward has been made.

We pass to Section 6, which deals with offenses arising from the false labeling and advertising of foods and drugs. This takes the place of Section 6 of the 1938 Act, but includes certain modifications introduced by the Defense (Sale of Food) Regulations of 1943. In particular, it is laid down that a label which is calculated to mislead as to the nutritional or dietary value of a food misleads as to its quality. Further, it provides that the fact that a label contains an accurate statement of the composition of a food shall not preclude a court from holding that the label is misleading. These are two useful shafts in the enforcement armory.

Extension of Labeling-Regulation Power

To continue, Section 7 preserves the Minister's power to make regulations as to the labeling of food. But here we see an important new power in the extension of the provision to deal also with advertisements, which should be of considerable service to the community.

This survey of the act, so far as it deals with the composition of food, may be concluded by a reference to Section 47, which is entirely new. It is designed to deal with the misuse of the designation "cream" in relation to cream substitutes and excludes the use of the word "cream" from the description of substitutes resembling cream in appearance, or products containing them, unless they are labeled "reconstituted" or "imitation" cream, which terms are defined in the section. This is an over-all labeling provision which again should be of service to the consumer.

Though the rest of the amendments in the act are primarily of local interest, passing reference might be made to the fact that they include important changes for sampling and analysis (Sections 91-98), that penalties for offenses are increased (Section 106), and that a new definition of food appears in Section 135, namely:

New Definition of "Food"

"Food" includes drink, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food or drink or of such products, but does not include (1) water, live animals or birds, (2) fodder or feeding stuffs for animals, birds or fish or (3) articles or substances used only as drugs.

The inclusion of chewing gum in the definition has the effect of overruling a decision of the courts over 50 years ago that chewing gum was not a food. Of course, a different definition of food was then in operation.

Finally, mention must be made of the formation of a food hygiene advisory council (Section 82), which is an important innovation. It is designed to act as a consultative body in relation to food and drug legislation generally, and must be consulted by Ministers when making regulations dealing with labeling, food hygiene and the like. The section provides that the council shall include persons representing the public on food hygiene, and representing also food traders and workers in the food industry. Obviously, it is too early yet to indicate what influence the council is likely to have on the development of our legislation.

The act makes little change in the law relating to drugs,[4] other than in matters of detail such as have been mentioned in connection with foods in what has been said above. It might, however, be mentioned that whereas it has long been an offense to sell an adulterated drug, it now becomes an offense to offer or advertise for sale such a drug (Section 1).

Work of Food Standards Subcommittees

In my last report, reference was made to the work of the Food Standards Committee. The food-standards orders made prior to the 1955 act are kept in force by the provisions of Section 136, so these call for no comment. No new standards have been made recently, though some of the existing standards have been amended in detail. The Metallic Elements Subcommittee has been busy in the interval and has issued reports, published by Her Majesty's Stationery Office, reviewing and making recommendations as to limits for the content of arsenic, copper, lead, fluorine and zinc in foods. The Preservatives Subcommittee, likewise, has seen the publication of its important reports on the use of antioxidants and of colors in foods. I am glad to be able to tell you that the Minister has announced the government's acceptance of the recommendations in the report on colors, and we can look forward with some confidence to the issue of regulations restricting the use of colors to those on an approved list. Hitherto, our regulations merely banned the use of injurious colors without naming more than half a dozen. In the near future our law should become very similar to that operating in the United States and Canada.

In conclusion, mention should be made of a matter of considerable topical interest which has become the subject of a regulation this month, namely, the Flour (Composition) Regulations, 1956 (Statutory Instrument, 1956, No. 1183). These regulations, which come into force on September 30, 1956, provide that all flour intended for human consumption, whatever the extraction rate, shall on sale contain not less than 1.65 mg. of iron, 0.24 mg. of Vitamin B, and 1.60 mg. of nicotinic acid or nicotinamide per 100 grams and, except in the case of whole meal flour, between 235 mg. and 390 mg. of *creta preparata* per 100 grams. Exemption is, however, provided for flour used for certain prescribed purposes. The regulation implements the government's acceptance of the recommendations in the report of the panel on com-

[4] 6 Food Drug Cosmetic Law Journal 655 (September, 1951).

position and nutritive value of flour, which sat under the chairmanship of Professor Sir Henry Cohen (H. M. S. O., Cmd 9757). It marks an important milestone in the long controversy on white bread.

Praise for Food-Law Jubilee Celebrations

There my report can end! But I cannot close without recording my sincere congratulations to The Food Law Institute on the great and well-deserved success which attended the jubilee celebrations at Washington recently. In the United Kingdom we shall look forward with keen interest to fuller reports of the proceedings in the FOOD DRUG COSMETIC LAW JOURNAL. **[The End]**

MINTENER RESIGNS AS ASSISTANT SECRETARY OF HEALTH, EDUCATION, AND WELFARE

The following statement was released by Marion B. Folsom, Secretary of Health, Education, and Welfare, on September 27, 1956:

"It is a matter of deepest regret to me and, I know, to all my associates in the Department, that Bradshaw Mintener is resigning his position as Assistant Secretary of Health, Education, and Welfare.

"In the two years Mr. Mintener has held this post, he has made a great contribution to the work of this Department. The fine spirit of our organization, particularly in the field, is due in large measure to his activities. His sound advice on the problems of the Food and Drug Administration has been instrumental in laying a proper foundation for a greatly needed expansion of its activities which are so vital to everyone in the Nation.

"I am sorry Mr. Mintener could not stay longer in Government service."

On the same day, the White House, through James C. Hagerty, press secretary to President Dwight D. Eisenhower, made public an exchange of correspondence between the President and Mr. Mintener. Mr. Mintener's letter, thanking the President for "the opportunity and privilege of working with Mrs. Hobby and Mr. Folsom," stated in part:

"During our visit several weeks ago, I reminded you that my commitment to you to serve on your team as Assistant Secretary of Health, Education, and Welfare would be fulfilled in September 1956. I regret exceedingly that personal circumstances and conditions, of which you are aware, make it necessary for me to terminate my Federal Government service. . . . effective not later than October 10, 1956."

In his reply, Mr. Eisenhower accepted the resignation "with real regret," saying: "You have given unsparingly of yourself in carrying out the duties of your office—to the lasting benefit of many departmental programs. It is good to know that we can count on your continued support from private life during the months ahead."

New Measures of Control of the Traffic

By ALFRED L. TENNYSON

Chief Counsel, Bureau of Narcotics, Treasury Department

THE Narcotic Control Act of 1956 (Public Law 728, Eighty-fourth Congress, approved July 18, 1956) makes a number of important amendments to the federal narcotic and marijuana laws, designed to strengthen the operation and application of the federal system of controlling the traffic in these dangerous drugs.

Outstanding among these amendments are those which provide increased penalties for violations of the narcotic drug and marijuana laws. Thus, whoever commits, or conspires to commit, an offense against these laws not involving unlawful sale or importation (such, for instance, as so-called unlawful possession) is subject, for a first offense, to imprisonment for not less than two, or more than ten, years and in addition may be fined not more than $20,000; for a second offense, the offender shall be imprisoned not less than five, or more than 20, years and in addition may be fined not more than $20,000; and for a third or subsequent offense, the offender shall be imprisoned not less than ten, or more than 40, years and in addition may be fined not more than $20,000.

The unlawful sale or transfer or the conspiracy to sell or transfer (without official written order forms) of any narcotic drug or marijuana is punishable, for a first offense, by imprisonment for not less than five, or more than 20, years and in addition a discretionary fine of not more than $20,000, and for a second or subsequent offense, by imprisonment for not less than ten, or more than 40, years and in addition a discretionary fine of not more than $20,000. If, however, the offender had attained the age of 18 before the offense and the offense consisted of the sale, barter, exchange, giving away, or transfer of any narcotic drug or marijuana to any person who had not attained the age of 18 (or conspiracy to commit such an offense), the offender shall be im-

in Narcotic Drugs and Marijuana

Mr. Tennyson Addressed the Recent Annual Meeting of the American Bar Association Division of Food, Drug and Cosmetic Law, Held at Dallas

prisoned not less than ten, or more than 40, years and in addition may be fined not more than $20,000, even for a first offense.

The unlawful importation or bringing into the United States of any narcotic drug, or the receiving, concealment, etc. or facilitating of the transportation, concealment or sale of any narcotic drug after being imported or brought in, with knowledge that the same has been imported or brought in contrary to law (including conspiracy to commit any of such acts in violation of law) is punishable, for a first offense, by imprisonment for not less than five, or more than 20, years and in addition a discretionary fine of not more than $20,000, and for a second or subsequent offense, by imprisonment for not less than ten, or more than 40, years and in addition a discretionary fine of not more than $20,000.

The unlawful importation or bringing into the United States of marijuana, the smuggling or clandestine introduction into the United States of marijuana which should have been invoiced, or the receiving, concealment, etc. or facilitating of the transportation, concealment or sale of such marijuana after being imported or brought in, with knowledge that the same has been imported or brought into the United States contrary to law (including conspiracy to do any of the foregoing acts) is punishable, for the first offense, by imprisonment for not less than five, or more than 20, years and in addition by a discretionary fine of not more than $20,000, and for a second or subsequent offense, by imprisonment for not less than ten, or more than 40, years and in addition by a discretionary fine of not more than $20,000.

A special and drastic penalty is provided for the sale or transfer of heroin (diacetylmorphine or a salt thereof) by an adult to a juvenile. Thus, whoever, having attained the age of 18 years, knowingly sells,

gives away, furnishes, or dispenses, or facilitates the sale, giving, furnishing, or dispensing, or conspires to sell, give away, furnish or dispense, any heroin unlawfully imported or otherwise brought into the United States to any person who has not attained the age of 18 years, may be fined not more than $20,000, and shall be imprisoned for life or for not less than ten years, except that the offender shall suffer death if the jury in its discretion shall so direct.

The penalty for unlawful possession of narcotic drugs or marijuana on a vessel of the United States has been increased, for a first offense, to imprisonment for not less than five, or more than 20, years and in addition by a discretionary fine of not more than $20,000, and for a second or subsequent offense, to imprisonment for not less than ten, or more than 40, years and in addition by a discretionary fine of not more than $20,000.

No Suspension of Sentence—No Probation

The act does not permit suspension of the imposition or execution of sentence, or the granting of probation, in the case of the above-described offenses, except for that first offense where the mandatory minimum penalty of imprisonment is not more than two years.

In addition to revised penalties, the Narcotic Control Act of 1956 provides other enforcement aids and facilities designed to secure a greater degree of control of the drug traffic.

Section 101 of the act not only continues in effect the existing provision of law making it an offense for a transferee to acquire or otherwise obtain marijuana without having paid the requisite transfer tax, but also prohibits the transportation or concealment, or facilitation of transportation or concealment, of any marijuana so acquired or obtained.

Specific Authority Conferred on Officials and Agents

Section 104 of the act gives specific authority to the commissioner, deputy commissioner, assistant to the commissioner, and agents of the Bureau of Narcotics and to officers of the customs to carry firearms, execute and serve search warrants and arrest warrants, and serve subpoenas and summonses issued under the authority of the United States, and to make arrests without warrant for violations of any law of the

United States relating to narcotic drugs or marijuana, where the violation is committed in the presence of the person making the arrest or where such person has reasonable grounds to believe that the person to be arrested has committed, or is committing, such violation.

Section 201 of the act adds a new chapter (Chapter 68—"Narcotics") to Part I of Title 18 of the United States Code. Section 1402 of the new chapter provides for the surrender to the Secretary of the Treasury, upon just compensation, of all heroin lawfully possessed prior to the effective date of the act, within 120 days after such effective date, and all quantities of heroin not so surrendered shall be declared contraband, seized and forfeited without compensation.

Section 1403 of Chapter 68 prohibits the use of any communication facility in committing, or in causing or facilitating the commission of, or in attempting to commit, a violation of the narcotic or marijuana laws, the penalty being imprisonment for not less than two, and not more than five, years, with a discretionary fine of not more than $5,000. The term "communication facility" is broadly defined to mean any and all public and private instrumentalities used or useful in the transmission of writings, signs, signals, pictures and sounds of all kinds by mail, telephone, wire, radio, or other means of communication.

Section 1404 of Chapter 68 gives the United States the right to appeal from an order granting a motion for the return of seized property and to suppress evidence made before the trial of a person charged with a violation of the narcotic or marijuana laws, provided the United States Attorney shall certify, to the judge granting such motion, that the appeal is not taken for purposes of delay and that the appeal shall be taken within 30 days after the date the order was entered and shall be diligently prosecuted.

Search-Warrant Procedure

Section 1405 of Chapter 68 provides that in any case involving a violation of the narcotic or marijuana laws, a search warrant may be served at any time of the day or night if the judge or the United States Commissioner issuing the warrant is satisfied that there is probable cause to believe that the grounds for the application exist, and a search warrant may be directed to any officer of the metropolitan police of the District of Columbia authorized to enforce, or assist in enforcing, a violation of any of such provisions.

Section 1406 of Chapter 68 provides that whenever in the judgment of a United States Attorney the testimony of any witness or the production of books, papers, or other evidence by any witness, in any case or proceeding before any grand jury or court of the United States involving any violation of the narcotic-drug or marijuana laws is necessary to the public interest, he—upon the approval of the Attorney General—shall make application to the court that the witness shall be instructed to testify or produce evidence, and upon order of the court, such witness shall not be excused from testifying or from producing books, papers or other evidence on the ground that the testimony or evidence may tend to incriminate him or subject him to a penalty or forfeiture. The witness is granted immunity from prosecution for, or on account of, any transaction, matter or thing concerning which he is compelled, after having claimed his privilege, to testify or produce evidence except, of course, from prosecution for perjury or contempt committed while giving testimony or producing evidence under such compulsion.

International Movement of Addicts and Violators

Section 1407 of Chapter 68 regulates international border crossings by narcotic addicts and convicted violators of the narcotic or marijuana laws. Such persons—before departing from, or entering into, the United States—are required to register with the appropriate customs official or agent or employee; upon departure from the United States, each such person must obtain a certificate which is surrendered, upon returning to the United States, to the appropriate customs official, agent or employee. The penalty for failing to observe any of these requirements is a fine of not more than $1,000 or imprisonment for not less than one, nor more than three, years, or both.

Section 301 of the Narcotic Control Act of 1956 amends the Immigration and Nationality Act to add the offense of conspiracy to violate the narcotic-drug and marijuana laws to those offenses for which the convicted alien may be denied entry into the United States or be deported, as the case may be.

Enforcement-Cooperation Plan Extended

Section 302 of the act continued in effect an established plan of cooperation by the Bureau of Narcotics with the several states in

narcotic-law enforcement and, in addition, authorized the Secretary of the Treasury to conduct narcotic training programs as an integral part of narcotic-law enforcement for the training of such local and state narcotic-enforcement personnel as may be arranged with the respective local and state agencies. The secretary was also authorized to maintain in the Bureau of Narcotics a "Division of Statistics and Records" to accept, catalog, file, and otherwise utilize narcotic information and statistics, including complete records on drug addicts and other narcotic-law offenders which may be received from federal, state and local agencies, and make such information available for federal, state and local law-enforcement purposes. Federal agencies of the United States are authorized to make available to the Bureau of Narcotics the names, identification, and any other pertinent information which may be specified by the Secretary of the Treasury, or his designated representative, of all persons who are known by them to be drug addicts or convicted violators of any of the narcotic laws of the United States, or any state thereof. The Commissioner of Narcotics is enjoined to request and encourage all heads of state and local agencies to make such information available to the Bureau of Narcotics.

[The End]

PUBLIC HEALTH SERVICE ESTABLISHES PSYCHOPHARMACOLOGY CENTER

Surgeon General Leroy E. Burney announced on October 16 that the Public Health Service, United States Department of Health, Education, and Welfare, has established a new unit to assist in the development of scientifically sound research programs on tranquilizing drugs and others used in the treatment of mental illness. The unit is called the Psychopharmacology Service Center in the National Institute of Mental Health, at Bethesda, Maryland.

Under the auspices of the institute, the center will be responsible for developing a nation-wide research program to stimulate support for basic research and for preclinical screening and testing of tranquilizing and other phenotropic drugs. Dr. Jonathan O. Cole has been appointed psychiatrist in charge of the center. As activities of the center develop, Dr. Burney said, technical assistance and research advisory services will be provided to scientists.

Dr. Cole received his psychiatric training at the Payne Whitney Clinic of the New York Hospital. After two years' service as an army psychiatrist, he joined the staff of the Division of Medical Sciences of the National Research Council.

Congress during 1956 appropriated $2 million for an intensive research program to study drugs used in treating mental illness.

By GLENN G. PAXTON

FOOD-ADDITIVES AMENDMENT AND COSMETIC

THE SUBJECT ASSIGNED to me is "Food-Additives Amendment of the Federal Food, Drug, and Cosmetic Act." Because this subject cannot be covered in detail in the time allotted, I shall attempt only to report generally on legislative developments to date, give some background material, and add some comments of my own. In this connection may I say that I am here as a member of this association, speaking only as a lawyer to his colleagues, and that the remarks I shall make have not been authorized by, nor are they to be charged to, any person or organization whom I may have represented at any time.

Hundreds of chemical substances are used in the manufacture of food for the American public. They are used for a variety of necessary and desirable purposes incident to the manufacture, preservation and distribution of food. Many have been used for generations, and are generally known to be safe. Salt and baking powder may be cited as common examples. New additives are constantly being developed, and many will be beneficial. Without the use of chemicals it would not be possible to manufacture and distribute the Nation's food supply efficiently, economically and in wholesome condition.

The Act in its present form prohibits the introduction into interstate commerce of any food that is adulterated, and provides that a food shall be deemed to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. If a food additive is such a poisonous or deleterious substance, its use in food is prohibited by the present Act, and the enforcement procedures of the present Act can be utilized. Enforcement difficulties under the present Act lie in the matter of proof. To determine the safety or toxicity of a new additive requires scientific laboratory experimentation which takes at least two years to complete. Even

OF THE FEDERAL FOOD, DRUG, ACT

The Author, a Partner in the Law Firm of Campbell, Miller, Carroll & Paxton, Chicago, Delivered This Address Before the Dallas Meeting of the Division of Food, Drug and Cosmetic Law, Section of Corporation, Banking and Business Law, of the American Bar Association August 28

if the Food and Drug Administration had the facilities for conducting this experimentation—which it does not have—it would still be faced under the present Act with the problem of first discovering what additives are being used and then spending the time necessary to perform the experimentation, during which time an additive which might eventually prove to be harmful might be used.

Witnesses testifying before the House Delaney Committee in 1950 expressed the opinion that while the food and chemical industries have proceeded with commendable caution in determining the safety of new food additives, the possibility exists that new additives might be used without adequate pretesting to prove their safety. The Delaney Committee report recommended legislation to require pretesting before use. To date there is no substantial evidence that these fears were justified. Notwithstanding the clamor of the food faddist and the pitchman with a special product for sale, our food supply is good and it has been safe. No scandals have grown out of the use of food additives. We are the best-fed nation in the history of the world, and the span of life continues to lengthen.

Regardless of statutory requirements or the absence thereof, the responsible food manufacturer does not now use a new additive until he is convinced of its safety through experimentation and pretesting. In addition to humanitarian considerations, there are good business reasons for this policy. The good reputation of the food manufacturer

is one of his principal assets. It is easily sullied and must be jealously guarded, for once lost it cannot be regained.

Indicative of the concern of food industries with the protection of public health, about four years ago the governing bodies of leading organizations representing the baking industry, the dairy industry, the meat industry, the milling industry, the grocery-manufacturing industry, the shortening and edible-oils industries and the restaurant industry, as well as the American Farm Bureau Federation, adopted statements of principles favoring the amendment of the Act to require adequate pretesting of new food additives by the user and review of the pretesting data by government before use.

1956 Subcommittee Hearings

Various bills on this subject were introduced in the Senate and House in the Eighty-fourth Congress and prior Congresses. The only hearings held on any of these bills were held before a subcommittee of the Committee on Interstate and Foreign Commerce of the House during January and February, 1956, under the able chairmanship of Representative J. Percy Priest of Tennessee. These hearings were fairly extensive and were concluded, but no report was made by the committee. Now that the Eighty-fourth Congress has adjourned, the results of these hearings are problematical. It can safely be predicted, however, that some or all of the same bills, with or without modification, and perhaps new bills on the same subject, will be introduced in the next Congress. Therefore, some consideration of the former bills and of developments in the hearings may be useful for the future.

All of these bills were similar in broad outline. Each would amend the Act, each contained a definition of "chemical additive" or "new food additive," each excepted pesticide chemicals on raw agricultural commodities (which were covered by a 1954 amendment) and each would prohibit the introduction into interstate commerce of the defined additive unless the same had been pretested and the pretesting data had been submitted to the Secretary of Health, Education, and Welfare for evaluation.

Naturally, there were differences in the various bills and in the viewpoints of interested parties. Many of these differences were of comparatively minor significance and should be susceptible of settlement in conference. Principal points of difference related to questions of definition and coverage, the question of functional value, and questions of procedure and court review.

Turning first to the troublesome question of definition and coverage, it was generally conceded that additives whose safety has been established by long usage or other means should be exempt. To require two years or more of experimentation on the many safe additives now in use, and approval thereof by FDA as a condition to continued use, would entail prohibitive expense, swamp the Food and Drug Administration and seriously disrupt the food supply of the Nation. Consequently, all of the bills contained language designed to provide an exemption for such additives. To illustrate, H. R. 8275, which was supported generally by industry and was fairly typical in this respect, would apply only to new food additives, and defined "new food additive" in part as any substance which becomes, or could reasonably be expected to become, a component of any food and which "is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of food, to be safe for use under the conditions of such use or intended use."

The quoted language, which in effect provides an exemption for additives of generally recognized safety, finds its origin in the new-drug provisions of the Act, and at first glance may seem adequate. But the words "generally recognized" are so vague and ambiguous as to cast doubt on the validity of the legislation and would, in any event, present real difficulties in the case of food additives. How could a manufacturer prove general recognition by experts, except possibly in the case of substances of long, widespread use? Under this language, would recognition of safety be required of all qualified experts in the United States, including those who do not happen to be familiar with the particular substance or only of those who have had occasion to familiarize themselves with the substance?

These are basic jurisdictional questions which would have to be answered in each case in order to determine whether an additive is or is not covered by the law. Let us hope that before further action is taken on this legislation a more definite and workable standard will be devised to exempt safe additives already in use. Various suggestions have been made which are deserving of further study. One suggested practical approach would be to exempt all additives to the extent that the same were used in foods prior to a date to be specified in the amendment. There are strong arguments in support of this type of "grandfather clause," particularly since there is no evidence of harm from the additives now in use and since, if such evidence should be

developed, the present provisions of the Act would be available to prevent further use.

Passing now to the question of functional value, at least one of the bills provided in effect that the Secretary may not approve an additive unless he finds that it will serve a purpose useful to the consuming public. The Administration supports this provision, arguing in effect that pretesting requirements, no matter how carefully administered, would still leave some measure of risk in many cases, which the consumer should not be expected to assume without assurance of a compensating advantage. The position of industry in this respect was stated by one witness as follows:

> It is submitted that it would be a mistake to inject into legislation dealing with questions of safety or toxicity of foods questions as to the functional value of a given ingredient. Additives are used for coloring, for flavoring, as preservatives, emulsifiers, bleaches, sweeteners, tenderizers, and a variety of other purposes incident to the manufacture, preservation, distribution and sale of food. Whether an additive is safe is one question; whether it is useful is an entirely different question. Who is to judge, and by what standards?
>
> Whether an additive is useful is primarily a question for the manufacturer, who is more thoroughly acquainted with the manufacturing techniques and requirements of his products than is a governmental agency or official. It would seem obvious that if an ingredient is not useful in the manufacture, packaging, preserving, holding or distribution of a food, or is not desired by the consumer, it will soon be eliminated as an ingredient by the necessity of keeping costs of production down. But if it is safe, if in the judgment of the manufacturer it serves a useful purpose, and if the consumer wants it, the manufacturer should not be denied the right to use it nor the consumer to purchase it merely because in the opinion of a Governmental agency or official it does not have functional value. The purpose of this legislation is to insure safety in foods—not to put Government in the business of regulating the personal tastes and likes and dislikes of the consuming public.

Procedural and Court-Review Bills

The third and most controversial question, and by far the most important, involving fundamental concepts of government, concerns procedure and court review. In this area the bills followed two general patterns.

One pattern, supported by FDA, would empower the Secretary, on application, to issue an order approving the use of the additive and specifying the conditions of use, or disapproving its use, and would make it illegal to use the additive except in compliance with the Secretary's order. The right of review of an adverse order would be limited to an administrative hearing before the Secretary, with an appeal to the United States Court of Appeals under the familiar rule that the findings of the Secretary, if supported by substantial evidence, would

be binding on the court. Industry witnesses contended that the practical effect of an amendment in this pattern would be to grant to FDA virtually unlimited control or licensing power over food manufacturers in this most important area of scientific progress.

Bills in the other pattern, supported by industry, when amended to incorporate minor changes recommended by industry, would prohibit use of a new additive unless it has been adequately pretested and thereby shown safe for use under the conditions of its intended use, and unless the pretesting data is first submitted to the Secretary and the Secretary given an opportunity to evaluate the data. They would require the Secretary within a specified period of time to issue an opinion as to the adequacy of the pretesting to show safety; would provide that if such opinion is adverse, use of the additive would be prohibited except on advance notice to the Secretary or pursuant to a court judgment of safety; and would provide that the enforcement remedies under the present Act would be available to the Secretary and also that either the Secretary or the manufacturer would have the right to institute an action under the federal Declaratory Judgments Act for a determination of the adequacy of the pretesting to show safety.

The bills in the second pattern were designed to give to the courts, and not to the agency, the power to test the validity of the initial opinion of the agency. It would be presumptuous to labor the question of administrative hearing v. court trial before this audience, but it may be appropriate to list some of the arguments for and against the administrative hearing procedure which were advanced by witnesses in the hearings.

Industry witnesses made the following points, among others:

(1) Administrative hearings are slow, tedious and costly; conducted with little or no regard for basic rules of evidence; and lack the power of the courts by orderly pleadings and pretrial procedures to narrow the issues and shorten the record.

(2) An administrative hearing to be conducted by the agency would be useless in this situation. Here the agency would have had possession of the manufacturer's scientific data for months, and would have reviewed it before rendering the initial decision. Nothing would be gained by a review of the same evidence by the same agency. In this respect the position of the agency would differ materially from

the quasi-judicial, nonadversary capacity in which other agencies are empowered to conduct administrative hearings under other statutes.

(3) The administrative hearing procedure places too much dictatorial power in the hands of the enforcement agency. Regardless of the weight of the evidence, the natural inclination of an enforcement official to hold to his original opinion will inevitably influence his decision in a subsequent administrative hearing in which he may directly or indirectly participate. The net effect of an administrative hearing in this situation would be to enable the agency to create a presumption in favor of the validity of its initial opinion.

(4) An administrative order on a technical subject will almost always if not always be affirmed by the courts on appeal, even though contrary to the weight of the evidence. On factual and technical questions reviewing courts have virtually abdicated in favor of governmental agencies. The Administrative Procedure Act and the Supreme Court decision in the *Universal Camera* case (340 U. S. 474) have not reversed the trend. Thus, the manufacturer would be denied the right to an impartial decision in accordance with the weight of the evidence.

The principal arguments advanced by advocates of the administrative hearing procedure, and the answers made thereto in the hearings, were as follows:

(1) The courts do not possess the scientific judgment needed to pass on the technical questions involved.

The answer was that if review of the decision were to be had in an administrative hearing and if the hearing were to be anything but a farce, the decision would have to be made on the record and not on what the agency staff knows or thinks it knows about the subject; that courts are better trained to weigh evidence than the Secretary, who is not required to be either a scientist or a lawyer; and that our courts repeatedly pass on equally difficult scientific questions in patent cases and other types of litigation, weighing the testimony of experts as they would here.

(2) The declaratory judgment procedure would produce a multiplicity of suits and would impose upon the agency a heavy burden of filing suits.

The answer was that the requirement of notice to the Secretary of intended use before the additive could legally be used after an adverse opinion by the Secretary would limit agency suits to those cases in which the manufacturer gives notice of intended use and that, with his

reputation, good will and consumer acceptance at stake, the manufacturer will follow that course, or himself institute suit, only in those cases in which he is convinced that the agency has acted arbitrarily. Instead, he will conduct additional experimentation and continue to seek agency approval.

(3) The declaratory judgment procedure would entitle the proponent of an additive to a jury trial, which would be undesirable.

This objection was answered by citation of authorities to the effect that if the issue in a declaratory judgment proceeding is not a common law issue but is an equity issue, an admiralty issue or, as here, a statutory issue, there is no right to trial by jury.

(4) The provision for declaratory judgment proceedings might not be constitutional.

In the opinion of industry counsel, this criticism was without legal basis, and it was fully answered. The answer is omitted here in the interest of brevity.

Other arguments for and against the administrative hearing procedure and the declaratory judgment procedure appear in the record, but the foregoing summarizes the principal arguments.

Industries' Stand on Cautious Draftsmanship

The industries affected deemed it vitally important, as a safeguard against unreasonable or arbitrary action by the agency, that if the agency opinion is adverse, the issue of adequacy of pretesting to show safety be initially tried in an impartial court and decided on the preponderance of the evidence; that this is important because presumptions inevitably arise in favor of an initial decision on a technical subject, whether rendered by an administrative agency or a court; and that it is of equal or greater importance that the agency staff member who passes upon the pretesting data in the first instance realize that the manufacturer can have a court trial, and that he may be called as a witness at the trial—which realization on his part would tend to promote a due regard for the rights of both the manufacturer and the public.

Nothing said here is to be taken as a reflection upon the present FDA, which is highly regarded. But permanent legislation vesting sweeping powers in an administrative and enforcement agency should be so drafted that constitutional guaranties will be preserved if an inept or corrupt agency administration should come into power.

These procedural problems involve fundamental philosophies of government. Our government is founded upon the doctrine of separation of powers. In the past few decades, we have witnessed increasing inroads upon the judiciary by administrative agencies through the administrative-hearing device. Where an administrative agency is given the power to sit in judgment on its own actions, to that extent we have abandoned the constitutional doctrine of separation of powers, and to that extent we have traveled the road to dictatorship.

The enactment of any of these bills would drastically change the law. Instead of assuming the burden of proof that an additive is unsafe, FDA would in effect say to the manufacturer: "You conduct the experimentation, you pretest the additive, you bring us the results and prove to us that it is safe; then, and not until then, may you use it." The result under any of the bills would be to invest FDA with new and tremendous powers over the most basic of all industries.

Complex Problems Arising Under Bills

Complex problems would be presented by enactment of any of these bills. "Toxicity" is a relative term. There are few, if any, absolutes in the field of toxicity. What is toxic for one person may be nontoxic for another. Foods universally recognized as safe are toxic if taken in sufficient quantities. Questions as to safe quantities or long-range effects of a food or food additive are not susceptible of exact determination under any known scientific method. Proof of adequacy of pretesting to show safety will present new and difficult problems.

Only a relatively few manufacturers have the laboratory facilities to conduct the required experimentation and to present the results in the form necessary to obtain FDA approval. The costs of installing and maintaining such facilities are exceptionally high. The proposed legislation might very well deprive the small manufacturer of the opportunity to develop new additives. Opinions differ as to whether technological progress in the manufacture and distribution of food would at least be retarded. Of course, the substantial costs of administration of, and compliance with, the new legislation would necessarily be passed on to the public.

If it be assumed that these consequences are justified by the need for the legislation, the situation nevertheless calls for the exercise of great caution in framing an amendment that will not stifle technological advancement or destroy constitutional rights and freedoms. **[The End]**

Science of Proof Under Food, Drug and Cosmetic Law

By ELWYN L. CADY, JR. . . . Who Addressed Food-Drug Men of ABA at Their Annual Meeting in Dallas on August 28. Mr. Cady Is a Medicolegal Consultant, of Kansas City, Missouri

A "CHAIN OF INFERENCES"—The basis for a recent Supreme Court decision [1]—leads our attention directly to the science of proof.

Selected for analysis by a method of the science of proof are three cases. One is a food case, the second a drug case and the third a dermatitis case.

Justice Clark, for the minority in *Cole v. Young*,[2] implies that there is something particularly sinister about a judicial interpretation "that admittedly rests upon a chain of inferences." [3] In the three cases to be analyzed, so also did counsel complain that inferences formed chains. Is there something "bad" abount catenate inferences? For an answer, we must turn to the science of proof.

As most of you already know, elucidation of the science of proof as a distinct inquiry in systematic terms was the work of Wigmore. His volume, first styled *Principles of Judicial Proof as Given by Logic, Psychology, and General Experience and Illustrated in Judicial Trials*, was originally published in 1913, later revised [4] and finally brought out as *The Science of Proof* [5] in 1937.

[1] *Cole v. Young*, 351 U. S. 536, 76 S. Ct. 861 (1956), reviewed in 42 *American Bar Association Journal* 764 (1956) as "one of the most important decisions in the term of the Supreme Court just ended."

[2] At pp. 877-878.

[3] Justice Harlan, for the majority, had stated, at p. 873: "We recognize that this interpretation of the Order rests upon a chain of inferences drawn from less than explicit provisions."

[4] Wigmore, *The Principles of Judicial Proof or the Process of Proof as Given by Logic, Psychology and General Experience and Illustrated in Judicial Trials* (2d Ed., 1931).

[5] Wigmore, *The Science of Judicial Proof as Given by Logic, Psychology, and General Experience and Illustrated in Judicial Trials* (3d Ed., 1937).

Although the text retained a tentative flavor,[6] it became evident that Wigmore had produced an integrated scheme or science [7] coordinating relevant data concerned with the complexities of proof [8]—defined generally as the "ratiocinative process of contentious persuasion." [9]

Criminal proceedings commanded the bulk of Wigmore's analytical text.[10] Today, it is necessary to seek application of the science of proof in diverse areas of the law if students,[11] practitioners,[12] and judges [13] are to continue to profit from Wigmore's pioneering efforts.

Catenate Inferences

Before plunging into the food and drug cases, it is necessary to set out the fundamental definitions [14] as Wigmore uses them technically.

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[6] "In the first edition we were offered a *novum organum* for the study of Evidence *in tentative form only*. The second edition, being the fruit of seventeen years of testing by use, is not presented with this apologetic qualification, which was an unnecessary caveat in the first [italics supplied]." (Wilson, book review, 17 *Cornell Law Quarterly* 324-325 (1932).)

". . . the suggestions are more tentative than authoritative, supported more by reasoning than by precedent." (Hutcheson, book review, 17 *American Bar Association Journal* 817-818 (1931).)

"The present work seems to have been the first attempt in English, since Bentham, to call attention to the principles of judicial Proof (distinguished from Admissibility) as a whole and as a system. It is therefore tentative. The chief service it aims to fulfill is to emphasize the subject as a science, and to stimulate its professional study." (Wigmore.)

[7] "These reasoning processes follow and are determined by certain principles which may be called the principles of judicial proof, and it is the analysis of these principles that constitutes the science of judicial proof." Battle, book review, 25 *Virginia Law Review* 120 (1938).

[8] It should be here noted that the term "proof" is used in numerous ways by different authors and practitioners. Of particular importance here is that Michael and Adler draw a strict distinction between "proof" and "persuasion." ("The Trial of an Issue of Fact," 34 *Columbia Law Review* 1224, 1237-1240 (1934); "Real Proof: I," 5 *Vanderbilt Law Review* 344-345 (1952).) This is in line with the terminology of Mill which should be contrasted with that of Wigmore. "Logic is not the science of belief, but the science of *proof* or *evidence*. Insofar as belief professes to be founded on proof, the office of logic is to supply a test for ascertaining whether or not the belief is well grounded." (Mill, *Philosophy of Scientific Method* (Abridged Ed., 1950), p. 11.) In the practical affairs of jury trials, however, Wigmore's concept is definitely more appropriate. Logic is only one component of proof, as dissected by Smith, and the other components—preconceptions, psychological, factual, legal and scientific—cannot escape consideration by the effective advocate. See Smith, "Components of Proof in Legal Proceedings," 51 *Yale Law Journal* 537 (1942).

[9] Wigmore, work cited at footnote 5, at p. 3.

[10] In Part V, "Mixed Masses of Evidence, in Trials, for Analysis," for example, eight of the nine cases are criminal trials. Also, there is an appendix "Evidence Problems from the Police Detective's Point of View" and one "Index of Police Science Articles and Books" (by Fred E. Inbau).

[11] Particularly those enrolled in courses in the science of proof in the Tulane law-science program (1949-1952), the University of Kansas City law-medicine program since 1952, and in contemplated courses at the University of Texas Law Science Institute.

[12] See O'Leary, "Science of Proof and the Rules of Evidence," 30 *Kansas City Bar Journal* 7 (September, 1955).

[13] See Lord Wright, book review, 24 *American Bar Association Journal* 478 (1938).

[14] It is submitted that Wigmore's technical usage makes for increased clarity and precision of thought in analyzing cases. This is not to say that other terms are not satisfactory. For example, we call attention to terminology of Michael and Adler, which may well be more precise for purposes of strict logic than that of Wigmore.

First, it should be noted that the science of proof deals with processes whereby the psychological fact [15]—proof [16]—is reached. To differentiate proof from inference,[17] Wigmore points out that proof "is the persuasive operation of the *total mass* of evidentiary facts, as to a *Probandum*" (or proposition to be proved), whereas "inference is the persuasive operation of *each separate* evidentiary fact." [18]

He illustrates these processes [19] by an analogy to antagonistic drugs which tend to counteract each other:

> Each dose is like an Inference; the Inferences offered by the opponent tend to counteract the effect of the Inferences offered by the proponent. After all the Inferences have been offered, the net effect on the mind of P (tribunal) is either Proof or not-Proof.

Wigmore continues: "The advocate asks the tribunal to infer; and the tribunal proceeds to infer; *i.e.* to think probatively, but this inference may or may not result in belief." [20]

In contrast to the exercises of the logic books:

> . . . in judicial trials it can rarely happen that the inferences offered are simple. The inference immediately next to the original *Probandum* will usually be made

[15] "The conviction or persuasion of the mind of a judge or jury, by the exhibition of evidence, of the reality of a fact alleged." (*Ellis v. Wolfe-Shoemaker Motor Company*, 227 Mo. App. 508, 55 S. W. (2d) 309, 312 (1932), cited in Black's Law Dictionary (4th Ed., 1951).) ". . . the citadel of final conviction, whether under a plaintiff's flag or a defendant's standard." (Smith, work cited at footnote 8.)

[16] See footnote 8. Also note that "proof" is not used synonymously with "evidence," though this usage is common among practitioners. For a technical discussion of the nature of evidence see Michael and Adler, "Real Proof: I," cited at footnote 8.

[17] Michael and Adler do not make this distinction: "We shall use the words 'proof' and 'inference' as names for the same process." ("The Trial of an Issue of Fact," cited at footnote 8, at p. 1270.) Also see "Real Proof: I," cited at footnote 8, at p. 346 ("The process which, from the point of view of jurors, is a passive affair of learning or inference and, from the point of view of litigants, an active affair of teaching or proof, is a single process.").

[18] Wigmore, work cited at footnote 5, at p. 9.

[19] "Actually 'inference' means the process of reasoning in reaching the fact and not the fact itself. In other words when we say an inference arises, we mean that there is sufficient evidence from which a particular fact may be inferred." (*Montgomery v. Hutchins*, 118 F. (2d) 661, 665 (CAA-9, 1941).)

"This process of arriving at an idea of what is absent on the basis of what is at hand is *inference*. What is present *carries* or *bears* the mind over to the idea and ultimately the acceptance of something else. . . . Every inference, just because it goes beyond ascertained and known facts, which are given either by observation or by recollection of prior knowledge, involves a *jump from the known to the unknown*. It involves a leap beyond what is given and already established." Dewey, *How We Think* (1933), pp. 95-96.

[20] Consider, for example, the application of *res ipsa loquitur* in food and drug cases (Goodspeed, "Application of the Doctrine of *Res Ipsa Loquitor* [*sic*] to Food Cases," 3 *Miami Law Quarterly* 613, 620 (1949) ("The view of the majority seems to be that it gives rise to a mere permissible inference of negligence.")). Thus, the tribunal may *infer*, but *belief* is not compelled. "The least effect which may be given to *res ipsa loquitur* is to permit the jury to infer from the plaintiff's case, without other evidence, that the defendant has been negligent. . . . The jury will be permitted to accept the inference, but it is not compulsory; if they see fit to find for the defendant, they are free to do so." (Prosser, "The Procedural Effect of *Res Ipsa Loquitur*," 20 *Minnesota Law Review* 241, 243-244 (1936).) See, also, Dickerson, *Products Liability and the Food Consumer* (1951), p. 123; Dierson and Dunn, *Product Liability Cases* (1955), p. 412.

from a fact which has itself been reached by an inference; and perhaps this inference in turn has been reached from another fact based on an inference. Such a series of inferences may be termed *catenate* (*i.e.* forming a chain).[21]

In symbols, this is represented by:

$$O \text{ - - - - - } > O_1 \text{ - - - - - } > O_2 \text{ - - - - - } > O_3 \text{ - - - - - } > P \textit{(robandum)}$$

The circles represent circumstantial evidence; the lines represent the offered inferences.[22]

Food and Drug Cases

Case 1.—Vaccarezza v. Sanguinetti [23] was a trichinosis case in which a mother and her two children allegedly contracted the disease by eating salami and coppe. The defendants attacked "chains in the reasoning processes of the trial court." [24] Under particular scrutiny were these inferences: [25]

(A) The mother and children contracted trichinosis. The trial court was asked to infer this from expert testimony offered as to the clinical diagnosis (1) corroborated by the patients' testimony (3) concerning symptoms (2). Note that the defendants offered the fact

[21] Wigmore, work cited at footnote 5, at p. 13. "The process of all evidence is an inference from one fact to the existence of another,—from Evidence to Proposition. . . . In the present class of evidence (testimonial evidence) the uniform feature is that the inference is to be drawn from the fact of an assertion having been made to the truth of the matter asserted."

Wigmore, *Evidence* (3d Ed., 1940), Vol. 2, Sec. 475, p. 515.

"Circumstantial evidence may be divided into two general types:

"1. A chain of circumstantial evidence (barely a sufficiency)—whereby if one link in the chain fails, the entire chain is broken. Each link must be proved beyond a reasonable doubt, because the strength of the whole chain depends on the strength of each individual link.

"2. A rope or cable of circumstantial evidence (more than a sufficiency)—whereby one fact does not necessarily depend upon another. Thus, the whole rope may have a probative value and sufficient strength even though one strand is weak. Therefore, one strand which was not proved beyond a reasonable doubt would not break the rope." Hopper, "Circumstantial Aspects of Arson," 46 *Journal of Criminal Law, Criminology and Police Science* 129-130 (1955).

"Although proof usually begins with the introduction of evidence, evidence by itself is always insufficient to resolve an issue of fact. A process of inference, in which the admitted propositions of real and testimonial evidence are ultimate *probantia*, must intervene." (Michael and Adler, "The Trial of an Issue of Fact," cited at footnote 8, at p. 1289.)

[22] In Wigmore's system of symbols, the addition of the arrowhead to the line represents the "provisional force" given the inference.

[23] 71 Cal. App. (2d) 687, 163 Pac. (2d) 470 (1945).

Other food cases have been analyzed in terms of successive inferences. See Jennings, "Probative Value of an Inference Drawn upon Another Inference with Special Consideration of Ohio Decisions," 22 *University of Cincinnati Law Review* 39, 43 (1953) (discussing *Mills Restaurant Company v. Clark*, 45 Ohio App. 25, 185 N. E. 470 (1933)). A note favoring application of a rule that "where direct evidence is available, an inference will not be permitted to be based on another inference" is found at 2 *Alabama Law Review* 339 (1950) (dealing with a food-poisoning case, *Goodwin v. Misticos*, 207 Miss. 361, 42 So. (2d) 397 (1949)). See also Dierson and Dunn, work cited at footnote 20, at p. 1030 (*Geisness v. Scow Bay Packing Company, Inc.*, 16 Wash. (2d) 1, 132 Pac. (2d) 740 (1942)).

[24] At p. 476.

[25] Here the court is using the California statutory definition of "inference" as the "deduction which the trier of fact makes from the facts proved." Compare the more precise distinction drawn at footnote 19.

that laboratory tests (biopsy) were negative (4, 5) as *denial;* [26] also, in *explanation* it was testified (6) that other disease combinations could produce similar symptoms (7).

(B) Salami and coppe were infested with larvae of *Trichinella spiralis.* The court was asked to infer this *probandum* from *probans* (A), together with a showing that no other uncooked pork or bear meat had been consumed at the time of infection (8, 8A). By way of *denial,* the defendants showed that laboratory analyses of remaining portions of the meat revealed no larvae (9, 10). The plaintiff's testimony (12) indicated that the husband and two "hired men" who also ate the meat did not develop clinical manifestations of disease (11). This was *explained* by testimony (14) that the men drank wine with the meat, thus minimizing chances of infection and also that they might have had a subclinical infection (13).

(C) Disease resulted from eating salami and coppe. "It is obviously a reasonable, if not inevitable, inference that if plaintiff wife and her two children were suffering from trichinosis (A) such disease must have been contracted from eating (C) infested salami or coppe (B) purchased from defendant retailer and manufactured by defendant wholesaler. No other inference is reasonably deductible from the record." [27]

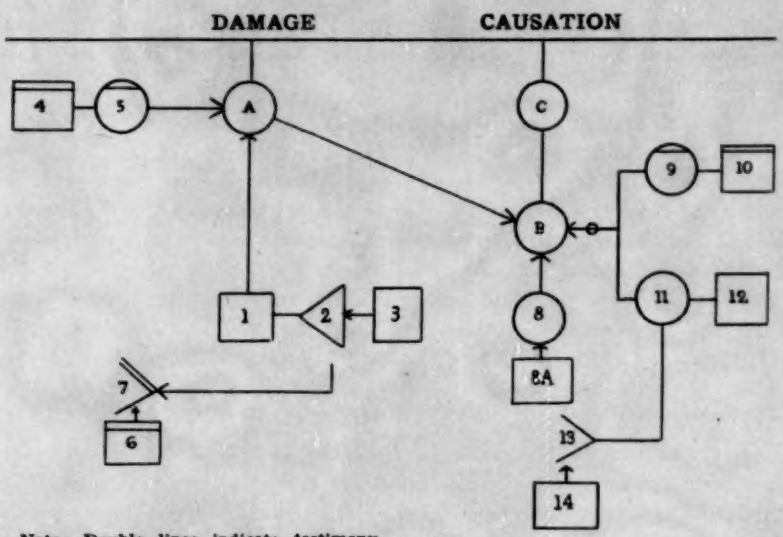
Using Wigmore's symbols, the interrelations of these inferences are as set out in the chart on the following page.

The defendants contended that because "inferences were based on other inferences" the trial court's reasoning processes were faulty. Presiding Justice Peters, however, in affirming judgment for plaintiffs, disposed of this claim:

> It may be true that some of the other facts here found to exist are based on circumstantial evidence and that such facts are used as a basis of proving, by inference, other facts. But the mere fact that a found fact is based upon circumstantial evidence and is used as a partial basis for another found fact does not of itself violate the reasoning processes permitted by our law. . . . The statement appearing in some cases that an inference cannot be based upon an inference, usually without citation and certainly without adequate discussion, does not and cannot mean that an inference cannot be based upon a fact which is itself based upon circumstantial evidence. If that were the rule it would mean that few cases based on circumstantial evidence could ever be tried because it is seldom indeed that but one fact, in such a case, is based on circumstantial evidence. If that were the rule the hundreds of decisions in our books affirming judgments where the findings contain a series of facts each proved by circumstantial evidence would

[26] The terms "denial" and "explanation" are used by Wigmore in a technical sense in setting out the four fundamental probative processes: assertion, explanation, denial and rivalry. See Wigmore, work cited at footnote 5, Secs. 15-16.

[27] *Vaccarezza v. Sanguinetti,* cited at footnote 23, at p. 474.



Note: Double lines indicate testimony offered by the opponent.

necessarily be wrong. Nearly all departments of reasoning are based upon deducing one fact from another fact that has itself been deduced from a prior fact. The only fallacy that may occur in such reasoning is where a deduced fact is based upon circumstantial evidence that is unreliable, is too remote or is too conjectural. The true rule is and should be that an inference cannot be based on an inference that is too remote or conjectural. In a civil case, if the first inference is a reasonably probable one it may be used as a basis for a succeeding inference. . . .

In the present case each fact found by the trial court, although many of them are based on circumstantial evidence, is a reasonable and probable deduction from the evidence. The deductions or inferences are not too remote or too conjectural. They are not based on guesswork, but on reasonable probabilities.[28]

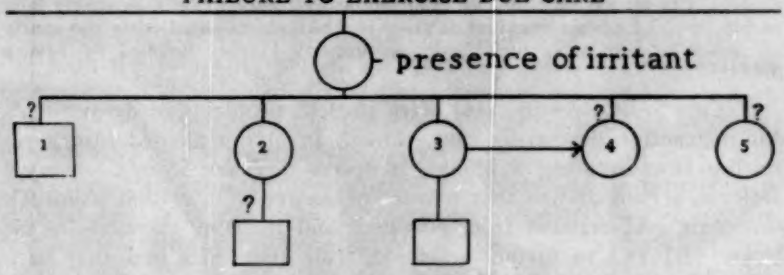
Case 2.—Henderson v. National Drug Company[29] found a patient joining his physician and the drug company as defendants. The doctor had given the patient an injection of liver concentrate and, subsequently, an abscess developed at the site of injection:

The conclusion plaintiff contends for against the Drug Company is based on this succession of inferences: (1) Dr. Grahn's inference that "there must have been an irritant in the injection I gave him." (2) The inference that this irritant was not an over-dose of the liver concentrate. (3) The inference from the testimony of Dr. Grahn and his technician, Miss Purnell, in respect to the

[28] At pp. 476-477, 479.
See note 17 *Southern California Law Review* 63 (1943), analyzing the previously confused state of the law in California on this point.
[29] 343 Pa. 601, 23 Atl. (2d) 743 (1942).

sterilization of the syringe and needle used on the plaintiff that these were thoroughly sterile. (4) The inference that this sterilization eliminated the presence in the instruments of either a chemical *or* a mechanical irritant. (5) The inference that this irritant got into the concentrate before it came into Dr. Grahn's possession. (6) If all the preceding inferences are accepted, then the inference is to be drawn that the defendant Drug Company "negligently [as charged] failed to use care to see that the drug was safe and fit for the intended purpose." [30]

A possible arrangement of these inferences symbolically is:



Note: A question mark means that the proposed inference represented by the line is in doubt.

Justice Maxey, who had vigorously rejected the doctrine that "an inference upon an inference will not be permitted" in *Neely v. Provident Life & Accident Insurance Company*,[31] here held for the defendant drug company:

> The ultimate inference that plaintiff's injuries were due to the Drug Company's failure to use due care in the preparation of the liver concentrate is based on so many weak intermediate inferences which do not exclude other equally reasonable inferences that it cannot be accepted as meeting the required measure of proof. The inference that the Drug Company failed to exercise due care in the preparation of the liver concentrate is not so compelling as to exclude the equally reasonable inference that Dr. Grahn did not exercise due care in its use.[32]

In discussing the rule as to burden of proof, the court quotes from one of its previous decisions:[33] In a *civil* case the evidence of facts and circumstances on which plaintiff relies and the inferences logically deductible therefrom must so preponderate in favor of the basic proposition he is seeking to establish as to exclude any equally

[30] At pp. 746-747.

[31] 322 Pa. 417, 185 Atl. 784 (1936), noted in 11 *Temple Law Quarterly* 255 (1937).

[32] *Henderson v. National Drug Company*, cited at footnote 29, at p. 747.

[33] *Whigham v. Metropolitan Life Insurance Company*, 343 Pa. 149, 22 Atl. (2d) 704, 707 (1941).

well-supported belief in any inconsistent proposition.[34] A source of confusion, however, is introduced by reference to Judge Lockwood's dictum in *New York Life Insurance Company v. McNeely*,[35] wherein he stated:

> But when an inference of the probability of the ultimate fact must be drawn from facts whose existence is itself based only on an inference or a chain of inferences . . . all prior links in the chain of inferences must be shown with the same certainty as is required in criminal cases, in order to support a final inference of the probability of the ultimate fact in issue. . . . *the prior inferences must be established to the exclusion of any other reasonable theory rather than merely by a probability* . . . a certain quantum of proof is arbitrarily required when the courts are asked to take away life, liberty or property [Italics supplied by Justice Maxey].[36]

Case 3.—Cosmetic cases often present problems of dermatitis.[37] An instructive dermatitis case, though involving alleged injury resulting from wearing a blouse, is *Marra v. Jones Store Company*.[38] Defense argument was that it was "necessary to infer that plaintiff's dermatitis [A] resulted from poisonous and irritating chemicals in the blouse [B] and to further conclude, from that inference, that such poisonous and irritating substances not only caused the dermatitis but that they were present in the blouse when that garment was sold by defendant [C]; that to arrive at the second conclusion is to pile inference on inference."[39]

The Kansas City Court of Appeals, in affirming a judgment for the plaintiff,[40] rejected the so-called rule against the "piling" of inferences, citing a leading Missouri case, *Van Brock v. First National Bank in St. Louis*.[41] That case had adopted Wigmore's viewpoint:

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[34] *Henderson v. National Drug Company*, cited at footnote 29, at p. 748. It is submitted that this represents the proper rule of law as regards the requisite "quantum of proof" in these cases. See Pound, commenting on *Silvers v. Wakefield*, 176 Kan. 259, 270 Pac. (2d) 259 (1954), in 14 *NACCA Law Journal* 99 (1954): "In a civil case what the burden of proof calls for is establishment of the disputed fact as in reason the most probable. To call for exclusion of any other reasonable inference than what is sought to be established is to apply the measure for criminal cases."

Alternative statements of the quantum of proof have been offered. For example, a general rule that "reasonable inferences can be based on reasonable inferences" has been suggested (note, cited at footnote 31, at p. 259 (1937)). ". . . the test of *reasonableness*, in the process of basing inferences upon inferences, can only mean that each successive inference must reasonably follow from the prior one. As long as that requirement is met there is no fear of coming to an unreasonable conclusion." (At p. 258.) See also *Gutierrez v. Public Service Interstate Transportation Company*, 168 F. (2d) 678 (CCA-2, 1948).

[35] 52 Ariz. 181, 79 Pac. (2d) 948 (1938).

[36] At p. 954 as quoted in *Henderson v. National Drug Company*, cited at footnote 29, at p. 747.

[37] Schwartz and Peck, *Cosmetics and Dermatitis* (1946). See *Ingham v. Emes* (1955), 2 All E. R. 740, noted in 23 *Medico-Legal Journal* 120 (1955).

[38] 170 S. W. (2d) 441 (Mo. App., 1943).

[39] At p. 450.

[40] The opinion was quashed by the Missouri Supreme Court in *State ex rel. Jones Store Company v. Shain*, 352 Mo. 630, 179 S. W. (2d) 19 (1944), holding that Missouri jurisprudence did not permit recovery under a theory of implied warranty in this type of case involving an undisclosed latent defect.

[41] 349 Mo. 425, 161 S. W. (2d) 258 (1942).

It is doubtful that there is any such rule of evidence or practice. 1 Wigmore, Evidence, Sec. 41, pp. 434-440. But, if it exists it is merely a phrase or legal slogan meaning that "an inference cannot be based upon evidence which is uncertain or speculative or which raises merely a conjecture or possibility," or that an inference must be supported by a known or established fact. Perhaps it is a convenient way of guarding against what the court considers "attenuated reasoning" or of disposing of evidence which the court regards as too remote or uncertain or lacking sufficient probative force to establish or prove the ultimate fact at issue. 95 A. L. R. 162-196 . . . .[42]

As Justice Jackson said, "In any event, rules of evidence as to inferences from facts are to aid reason, not to override it."[43]

In plotting the inferences in *Marra v. Jones Store Company* (see the chart on the following page), an additional piece of circumstantial evidence should be included (D) ("the garment had not been in contact with any other object or thing from the time it was sold by defendant until plaintiff donned it").

From this consideration of catenate inferences as they appear in food and drug cases, let us ourselves infer and see if we can justifiably arrive at certain conclusions:

(1) The fact that a chain of inferences (or line of proof[44]) appears in a trial or appellate disposition of a case is not, in itself, ground for holding the result reached improper.

(2) Most cases *do* involve catenate inferences, so that there is no virtue in criticizing the reasoning processes of jurors or judges when a chain of inferences is present.

It is further suggested, in a more tentative vein, that the following *probanda* may very well have validity:

(1) Of significance for the lawyer marshaling evidence in a food, drug or cosmetic case is a consideration that each and every *probandum* in a chain of inference must be established by the appropriate quantum of proof through evidence that is not held to be "too remote or speculative."

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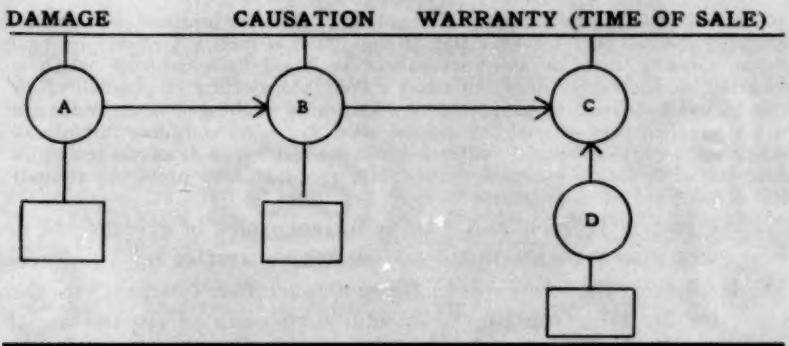
[42] At p. 261.

"If the cases are examined upon their facts it will be seen in nearly all of them that what the court was really determining, was whether or not all of the evidence taken together would justify the desired conclusion." (Fuson, "Evidence—Inference upon an Inference (Missouri)," 27 *Washington University Law Quarterly* 130-131 (1941).) See, for example, *Gears v. State*, 203 Ind. 380, 180 N. E. 585, 590 (1932), wherein Judge Treanor stated:

"It is necessary that we leave to the sound judgment of the jury, some margin for logical grouping of facts for the purpose of drawing inferences of fact, *and for the utilizations of these inferences of fact with other facts as the basis of further inferences of fact.* After all the 'logic' or 'reason' which we should expect of the jury is largely a common sense evaluation of the probative of all the evidence in the light of every day experience and observation." (Quoted and italicized in note, 8 *Indiana Law Journal* 203, 205 (1932).)

[43] *Maggio v. Zeitz*, 333 U. S. 56, 66, 68 S. Ct. 401 (1948).

[44] Michael and Adler use this designation ("The Trial of an Issue of Fact," cited at footnote 8, at p. 1274).



(2) From the standpoint of the judge or jury, if each *probandum* in a chain is thus sufficiently established, on logical grounds the ultimate *probandum* may actually be strengthened.[45] On the other hand, each additional "link" in the chain increases the possibility that sufficient evidence to establish a given "link" may not be forthcoming. As a practical matter, therefore, proof is more elusive where the case comprises a long chain of inferences.[46]

Food, drug and cosmetic litigation deserves critical analysis by the methods of the science of proof. Present limitations of space prevent us from exploring its application further. I do trust, however, that the approach of the science of proof under food, drug and cosmetic law has been helpfully illustrated. **[The End]**

[45] At pp. 1285 and following, where Michael and Adler develop a "calculus of probability."

"Since we can never have all of the knowledge relevant to such propositions, the more knowledge we have the greater the worth which we attach to the probability value that is determined in the light of this knowledge. The probability value of a proposition does not necessarily always increase when it changes at successive times, since disproofs may overbalance proofs. But the worth of probability values always increases with successive proofs and disproofs, since it is a measure of the total knowledge without regard to the differential amounts of favorable and unfavorable knowledge." (At p. 1288.) See Keynes, *A Treatise on Probability* (1921), p. 72: "Starting, therefore, with minimum weight, corresponding to *a priori* probability, the evidential weight of an argument rises, though its probability may either rise or fall, with every accession of relevant evidence."

[46] At p. 1292: ". . . the greater the number of steps of circumstantial proof, the greater the likelihood that one or another general proposition will fail of proof or judicial notice." See also Smith, work cited at footnote 8, at p. 564: "One should prefer evidence which leads to the desired conclusion by means of the smallest number of intermediate inferences. As the chain of inference lengthens, the certainty of sequence tends to diminish and the strain on credulity and understanding increases."

SOME LABORATORY PROBLEMS in Connection with Food and Drug Law Enforcement

By H. A. WATSON

Mr. Watson Emphasizes the Necessity for Keenness in the Analysts' Checking for Food and Drug Violations, and That This Need Can Be Met Only by a Scientific Staff of High Calibre

IN THE EARLY DAYS of aviation before instruments were available, bush pilots claimed that they "flew by the seat of their pants." One might also say that during the Middle Ages the beer inspectors who tested the beer by wearing leather breeches and sitting in it were "testing the beer by the seat of their pants." However, chemical technology has traveled a long way since that time, and in recent years control of the quality and purity of our food and drugs has been further promoted by the introduction of complex chemical equipment and electronic instruments of various kinds besides the development of new techniques, such as chromatography and electrophoretic methods.

Scientists in various countries employed in administering food and drug acts are, of course, just as familiar with these modern instruments and the latest techniques as are their counterparts in industry, or certainly they should be. To be really effective in their work, they should be constantly on the watch for even newer methods.

While it is true that a whole host of ethical firms are equally interested with food and drug officers in the manufacture and sale of wholesome products completely meeting legal standards, it is recognized that many may use these new techniques for their own advan-

The Writer Is Regional Director of the Canadian Food and Drug Directorate, at Winnipeg

tage, and the mental alertness and experience of the government analyst—if he uses these attributes to the full extent—may serve to show up illegal practices. An instance, many years ago, is recalled of a maple syrup which met the requirements for lead number, ash, etc., and thus appeared to be a genuine maple syrup but which, owing to a different rate of settlement of the lead precipitate and a differential division of color between liquid and precipitate, aroused suspicions as to its true character. It was eventually shown to be maple syrup cleverly adulterated with ordinary sugar syrup and caramel to meet the numerical values in the standard.

The necessity for keenness in the analysts' checking for violations of the Food and Drugs Act is well illustrated, of course, in our own directorate. Within the last few years, a small section of the trade believed that they might safely adulterate butter with a certain amount of foreign fat, in the belief that this amount could not be detected by the existing Reichert-Meissl and Polenske numbers. The directorate was able to develop a more sensitive method based on the tocopherol content of the added vegetable oils and thus bring to a satisfactory conclusion an enforcement problem.

While some products of simple composition offer no special difficulty to the analyst, others may have to be watched carefully, especially at times of shortages brought on by war or other conditions. Olive oil in short supply was occasionally replaced by various other oils at such times. The classic example of detection which comes to mind is that carried out by the United States Food and Drug Administration some years ago when it was proved that the constituent squalene—naturally present in olive oil—was, in the case under study, actually added to deceive the analyst. Anthraquinone was added as

a tracer to squalene purchased by the defendant company, the addition being unknown to them. The presence of the tracer was then established in the adulterated oil which was itself chosen to resemble olive oil in respect to some of its physical characteristics, refractive index, etc.

The whole operation illustrated a deliberate attempt to produce an oil which might pass detection as olive oil but which was defeated by teamwork between the scientific staff and inspectors of FDA and the company manufacturing the squalene.

Special Techniques for Detection of Adulteration

As illustrated by the example of the butter, standards themselves are not always sufficient to detect adulteration, and any known method or technique available should be used to thwart those who are known to be deliberately adulterating their product. A rather persistent adulteration of ground pepper by the addition of shell was detected by one of the regional offices in Canada some years ago, even though the shell was added in careful quantities sufficient to keep within the ash and fiber standards. Shipments of shell were being imported by the particular grinder, and there was no doubt that the shell was finding its way into the finished pepper. A method of detection developed by United States FDA officials, Messrs. Smith, Alfend and Mitchell, showed the ratio of MgO to crude fiber and to d-glucose was such as to establish the presence of added shell.

A rather interesting case arose a short time ago on a complaint that glass and some small lead pellets had been found in a brand of cheese. One of the staff with special knowledge of dairying procedures remembered the common practice in cheese plants of using a floating thermometer weighted with small shot, and the manufacturing firm remembered having broken one of their thermometers of this type, and the date and batch were traced.

The picture with respect to analysis of a simple product, such as vanilla flavor, has become considerably more complicated in recent years. At one time an extraction of the vanillin, followed by an ammoniacal extraction to detect the presence of any coumarin and a check for vanilla resins, gave a reasonably good idea of the composition. Since the coumarin ban, a number of related substances have been developed for flavoring purposes, some of which have not yet been proved to our directorate to be free from potential hazard, and

these require chromatographic and other procedures for their identification. Thus, in the matter of enforcement, the laboratory must keep pace with industry in being able to detect and identify these newer flavoring substances and indeed many other food additives which appear almost daily.

Specialized Studies in Pesticide Controls

Running parallel with United States developments in the control of pesticides under the Miller Amendment, our directorate has been concerned with the same problem, and certain tolerances have been set by appropriate amendment of the regulations. This creates problems in laboratory detection and assay of these pesticide substances for proper enforcement, and some special studies in this field have been made. The whole field will doubtless expand and become a quite considerable effort on the part of the technical staff in the future.

Another field which they may have to consider in this atomic age is the effect of radiation. Indeed imports of tuna and other fish from Japan, suspected of being possibly contaminated by "fall-out," were actually subjected to routine check at one of the regional offices at the Coast. Except for civil or national defense, this may not be a matter for too much concern at the moment, but when "radiation badges" for the general public are being spoken of, future concern with the food supply from this point of view will doubtless become inevitable.

Tracing Narcotics as to Origin

In the field of narcotics, which comes under different legislation but which is nevertheless administered by this department, an interesting laboratory operation in the matter of tracing the country of origin of samples of opium from different countries has served to show where the opium originated, and correct opinions are reported to have been given in about 95 per cent of the cases. This is a matter of considerable interest to the United Nations, to those working in the field of international control and to those responsible for narcotic-drug enforcement.

In conclusion it might be stated that the cases quoted from our Canadian experience probably differ very little from those encountered elsewhere but it was thought that they would show what some of the problems of the food and drug chemist are and how they are being

met. The future will bring new problems, but it is obvious from what has been said that the calibre of the scientific staff must be maintained at a high level in order to carry out the responsibilities for enforcement with which the directorate is entrusted.

Only in the future can it be determined how well the challenge is being met, but it is believed that in recent years commendable progress has been made. **[The End]**

DRUGS, DEVICES, COSMETICS—MISREPRESENTATION, PRICE DISCRIMINATION, EXCLUSIVE DEALING

Medicinal preparation . . . Misrepresentations as to the effectiveness of drug products in their treatment of arthritis and rheumatism are prohibited by an initial order and a consent order. (Initial order released October 5, 1956, in an action involving one company; consent order released October 10, 1956, in an action involving another.)

Drug products . . . Misrepresentation as to the value of a medicinal preparation in the treatment of colds is prohibited. (Released August 24, 1956.)

Weight-reducing aids . . . Advertising claims as to the effectiveness of weight-reducing products are challenged. (Issued August 22, 1956; released August 31, 1956.)

Birth-control calendar device . . . The seller of a birth-control calendar device agrees not to represent that its device will enable a woman to ascertain her fertile and sterile days. (Released September 21, 1956.)

Foot device . . . False claims as to the effectiveness of a device to relieve foot pains are to be discontinued. (Released September 21, 1956.)

Hair and scalp preparation . . . Representations that a hair and scalp preparation will prevent excessive hair loss and will restore scalp health are challenged. (Issued August 17, 1956; released August 25, 1956.)

Beauty preparations . . . A company, selling beauty preparations, which has a standard promotional program providing for discounts of up to 25 per cent for cooperative advertising and "push money" services rendered by the customer is charged with giving favored customers greater discounts. (Issued September 14, 1956; released September 26, 1956.)

Hearing aids . . . A manufacturer of hearing aids is charged with requiring its distributors not to handle competing products. (Issued September 11, 1956; released September 21, 1956.)—CCH TRADE REGULATION REPORTS ¶ 26,227; 26,232; 26,158; 26,172; 26,199; 26,194; 26,161; 26,207; 26,196.

Life in a Weights-and-Measures Jungle

FIFTY YEARS AGO the average food store carried no more than a few hundred different food items, the majority of which were not prepackaged. By far the greatest number of consumer items were weighed and packaged at the time the consumer made a purchase. If a person bought butter, lard or shortening, it would be ladled from a tub, weighed, and packaged. Crackers came in bulk in a barrel. Pickles, flour, sugar, fruits, potatoes, onions, meat, and practically all foods except a few canned items were delivered to the retailer in bulk, and he packaged these items for the consumer at the time of sale. Fresh fruits and produce were available only in season.

Contrast, if you will, the retail food store of 50 years ago and the modern supermarket as we know it today. The modern supermarket averages approximately 4,000 individual items available for sale to the consumer. In the supermarket of 1956, the purchase of a product which has not been prepackaged by the manufacturer or the packer is becoming increasingly rare. Refrigeration, improvements in packaging materials, and radical advancement in transportation and distribution facilities have made available to today's housewife a variety of products which would have seemed unbelievable to the housewife of 1906, or even 1926. The most revolutionary changes in the methods of processing, packaging and distribution of foodstuffs have occurred in the decade which has passed since the end of World War II.

If you can appreciate the magnitude of the evolution which has taken place in the merchandising of foods, you will undoubtedly recognize that the problems of a manufacturer of prepackaged foods have increased in the same proportion as the number of packages of product he sells. The manufacturer who distributes his product on a national basis is faced with laws and regulations of the federal government, of 48 state governments and of the political subdivisions of the

By ARTHUR C. O'MEARA

The Assistant General Counsel for Swift & Company, Chicago, Delivered This Talk on Packaged Foods Before ABA's Division of Food, Drug and Cosmetic Law, in August

several states. While weight laws, for the most part, are the same or substantially similar in content, in my experience there is a pronounced lack of uniformity in the interpretation and enforcement of said laws.

What are the weights-and-measures problems which arise in connection with prepackaged food items prepared by a manufacturer? It is well known that all foods contain moisture, and most of them to a very substantial degree. It is a further well-known fact that at any time there is less than 100 per cent humidity in the atmosphere, evaporation of moisture in a food product will inevitably occur unless the food is one which would fall into the category described as "hygroscopic." Hygroscopic foods under certain conditions will absorb moisture. The rate and amount of evaporation of moisture in foods will vary substantially, depending upon the relative humidity of the air, the temperature at which the product is held, the length of time the product is held and the nature of the packaging material. Only a product placed in a hermetically sealed moisture-proof container will escape the evaporation of moisture. So if you think of time as a dot moving along a line toward infinity and the weight of a product as a dot moving on a line of decreasing weight as its moisture content decreases, it becomes an inescapable fact that at only one given instant of time will the weight marked on a package be equal to the weight of the product in the package. The problem therefore may be stated as follows: 'At what point of time must the weight of the product equal the weight marked on the package?

All weights-and-measures statutes and regulations promulgated in pursuance of them have been enacted primarily in the interest and

welfare of the consuming public, and properly so. The consumer is entitled to protection against frauds perpetrated by irresponsible manufacturers and retailers and is further entitled to receive full value for his or her purchase. The primary obligation of the manufacturer, the retailer, and the weights-and-measures official is to the ultimate consumer. The question might well be asked, however: Are the present laws best suited to give such protection? For the answer to this, we must take a brief look at the law.

Section 403(e) of the Federal Food, Drug, and Cosmetic Act [1] provides that a food shall be deemed to be misbranded:

> If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

In pursuance of this section of the statute, the Food and Drug Administration has issued Regulation Section 1.8(j), which provides:

> Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

A typical state law may be found in New Jersey.[2] The New Jersey statute provides:

> No person shall distribute or sell, or have in his possession with intent to distribute or sell, any article of food in package form, unless the net quantity of the contents be plainly and conspicuously marked on the outside of the package in terms of weight, measure, or numerical count.
>
> Reasonable variations, tolerances, and exemptions as to small packages shall be permitted. The state superintendent shall by order fix such tolerances and exemptions as to small packages as shall have been or may hereafter be fixed by the secretary of the treasury, the secretary of agriculture, and the secretary of commerce of the United States of America.

Although there is a substantial number of years separating the enactment of the two above-quoted laws, you will note their similarity. Further, the New Jersey statute is fairly representative of the statutes of the several states.

These laws by all means should be administered in a manner which will lend itself to the most efficient methods of enforcement by public officials for the maximum protection of the ultimate consumer and, at

[1] 21 USCA, Sec. 343(e).

[2] New Jersey Statutes Annotated, Sec. 51:1-29.

the same time, be fair to the manufacturer. From my experience as an attorney, I believe that the methods of enforcement of the various laws may be broken down into three broad categories:

(1) Jurisdictions [2] following the rule set forth in the Federal Food, Drug, and Cosmetic Act, above quoted.

(2) Jurisdictions [4] recognizing a tolerance expressed in a fixed percentage.

(3) Jurisdictions [5] allowing no tolerances and maintaining that a product must equal 16 ounces to the pound regardless of the time it is purchased by the consumer.

Act Pronounces Best Rule of Law

Of the three categories, I respectfully submit that the rule pronounced under the Federal Food, Drug, and Cosmetic Act represents the best rule of law in that it adequately protects the consumer, it has flexibility which lends itself to more efficient administration on the part of public officials and, finally, it is a reasonable regulation to impose on manufacturers.

The jurisdictions which follow the principle of a fixed tolerance overlook the following salient points:

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[2] *Florida*—Regulation No. 2—"Packaged Goods"—Sec. A:

"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the package is weighed or measured, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure. The reasonableness of variations will be determined on the facts in each case."

Arkansas—Regulations (Food and Drug) (g)(1):

"Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into intrastate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure."

California—Deering's Business and Professions Code, Div. V, Ch. 6, Sec. 12614:

"When a commodity in a container is sold and there is a discrepancy between the actual quantity of the commodities in the container and the net quantity of the contents thereof indicated on the container or between the fill of the commodity in the container and the capacity of the container there is no violation of this chapter:

"(a) If such discrepancy is due to unavoidable leakage, shrinkage, evaporation, waste, or causes beyond the control of the seller acting in good faith."

Oklahoma—2 Oklahoma Statutes Annotated 5-43. This law is patterned after the California statute above quoted.

[4] Georgia Department of Agriculture regulation, effective January 1, 1956:

"The 1½% tolerance allowed for meat makes it almost impossible to figure the amount of error by ounces and, since it is so small, it has been broken down in order to prevent confusion between weights and measures officials and those interested in the sale of meat in package form. Inspectors will inspect packages in accordance with the following table, and it is furnished you for your benefit . . . ."

In other jurisdictions where tolerances and variations are authorized under the statute, fixed tolerances have been recognized as an administrative practice without the issuance of a formal regulation.

[5] For example, Louisiana, Vermont, Virginia, also New Jersey prior to March 21, 1955, at which time the Supreme Court of New Jersey held tolerances and variations were mandatory. See *State of New Jersey v. Hotel Bar Foods; State of New Jersey v. Safeway Stores, Inc.*, CCH Food Drug Cosmetic Law Reports ¶ 85,158, 112 Atl. (2d) 726.

(1) In any rule where a fixed tolerance is created, whether it be in weights and measures, the minimum fat requirements in milk, or any other similar-type regulation, there is a tendency for the minimum requirement to become the target at which to shoot and, therefore, instead of representing a point below the target which offers a cushion or margin of error, it automatically tends to become the maximum.

(2) The moisture naturally found in different foods may vary in content from 20 per cent to 80 per cent. It is unrealistic to apply to all products a fixed percentage of allowance for variations in weight. for the reason that such variation percentage presupposes that all products are going to vary in weight by the same percentage or degree. The variation which might be considered reasonable for a Virginia ham, which has a low moisture and high salt content, certainly could not be reasonable for a fresh eviscerated chicken, which has a relatively high moisture content. In order to be realistic, the reasonableness of the variation in weight due to loss of moisture must be judged on the basis of the facts of each individual case.

(3) The principle of allowing a fixed tolerance particularly discriminates against a manufacturer who distributes his product on a nation-wide basis. For example, let us assume that a state recognizes a tolerance in weights at a fixed 1½ per cent. Manufacturers distributing product in that state through channels of interstate commerce would have to sufficiently pack their product in order to guarantee that variations in weight while in the channels of commerce would not exceed the allowable tolerance. On the other hand, a local manufacturer would be in a position to weigh, package and deliver his product on the same day and, if he so desired, take advantage of the full tolerance. Under these conditions, at the time of delivery, his product in the package could be less than that which was marked on the package without being subject to penalty under the weights-and-measures law.

In spite of the three shortcomings above outlined, it can be said that the "fixed tolerance" rule is far more realistic than the "no tolerance" rule because it does recognize the inevitable facts concerning evaporation of moisture.

There seems to be no logical argument to support a regulation which recognizes no variations in weight that inevitably occur in good distribution practice. When a manufacturer packages a product he cannot know whether the consumer will buy the package from a retailer three days, three weeks or three months following the time it

is weighed and packaged. Yet he knows that with every passing hour there will be a slight variation in weight. For which particular day must a manufacturer be sure that the weight marked on the package will equal the weight of the product?

The "no tolerance" rule also fails to recognize the fact that you can take two identical products and place them in the hands of different retailers, and the difference in the handling of the product at the end of one week in all probability will result in there being a substantial difference in the weight of the two products. What I am saying here is that you can go into 50 different establishments and see product handled in 50 different ways. Storage and display facilities, with varying temperature and humidity conditions, may differ substantially in each of the 50 stores. Consequently, identical product placed in those stores on identical days will vary in weight at the end of a given period of time. The "no tolerance" rule ignores these facts. Certain of the "no tolerance" exponents have indicated that the manufacturer should overpack his package and so guarantee that it will be full weight at the time it is purchased by the consumer. But they do not tell you how much to overpack and for how long a period you must guard against variation in weight. Said jurisdictions also ignore the fact that while a package may be overpacked, this practice represents an additional cost which will be reflected in the price to the consumer.

Decisions Dealing with Tolerances in Weights

There have been a number of outstanding decisions dealing with this problem. As early as 1924, the Court of Criminal Appeals of Texas[6] held that the statute defining as a misdemeanor any variation between the marked weight on the package and the weight of the product in the package was unconstitutional where said statute did not provide for tolerances. The court reviewed the facts and discussed various types of products in which the moisture content would be affected by atmospheric conditions, and then made this memorable statement:

> There appear in this law no tolerances, no variations, no questions of knowledge, willfulness, intent to defraud, etc. It appears inevitable that the dealer in such articles would perforce have to weigh each package in his store every day and put thereon a new brand after each weighing, setting out the weight as of that day, according to whether the contents of such package had been increased or diminished in weight by the absorption or evaporation of moisture.

[6] *Overt v. State*, 260 S. W. 856, 858 (Ct. Crim. App. of Tex., 1924). Contra: *City of Seattle v. Goldsmith*, 131 Pac. 456 (Wash., 1913).

It seems to us that we need carry the argument no further. The statement of the facts carries with it its own irresistible conclusion against the soundness of this law. The condition referred to would be intolerable. The sale in this country of such stuffs in packages is imperative. The restrictions and conditions attempted to be imposed by this law are harsh and oppressive to such an extent as to render it practically incapable of enforcement and violative of the Fourteenth Amendment to the federal Constitution and section 13, art. 1, of our state Constitution.

Two years earlier the Court of Criminal Appeals of Texas [7] had held a defendant to be not guilty in a case involving 48-pound sacks of flour which weighed 47 pounds and 13 ounces at the time the product was weighed by the public official, on the ground that the statute required the establishment of reasonable tolerances, which the Commissioner had failed to do. In that case the court made the following statement:

The construction of the statute upon which the conviction rests appears that in the sale of flour no account is to be taken of reasonable variations in weight. Such an interpretation, we think, is not the necessary effect of the language of the statute in question. In our judgment, the Legislature intended that reasonable variations should be allowed, and made it the duty of the Commissioner of Markets and Warehouses to prescribe regulations therefor. It is true that the word "may" is used in the statute. This, however, is not conclusive against its mandatory effect, so far as the allowance of reasonable tolerances or variations in weight is concerned.

In 1936 a United States district court had occasion to interpret the Federal Food, Drug, and Cosmetic Act, and regulations promulgated in pursuance thereof, in a seizure action.[8] This court considered the mandatory nature of recognizing variations and tolerances as provided by law. The case involved a cheese manufacturer who had put up a product in half-pound packages. At the time the packages were check-weighed by the Food and Drug Administration, it was found that out of 60 packages selected at random, 59 were underweight, with an average deficiency of one fourth of an ounce. While the opinion of the court covers a number of important points of law, the decision had this to say about the law and regulations concerning variations and tolerances:

We need not go to the extreme of holding that any *excess* would also have been criminal, even though no such distinction appears in the text. But the proviso is there, and the proviso is expressed categorically: "reasonable variations shall be permitted." Permitted by whom? By the departments, says the Government. By the jury, says the defendant. "Tolerances" are to be established by departmental rules and regulations; and presumably these tolerances are to

[7] *Ex Parte Humphrey*, 244 S. W. 822 (Ct. Crim. App. of Tex., 1922).

[8] *U. S. v. Kraft-Phenix Cheese Corporation*, 18 F. Supp. 60 (DC N. Y., 1936).

determine the limits of reasonable variations; but whether so established or not, reasonable variations must be permitted.

. . .

It is the further contention of the Government that the matter of the reasonableness of the variation is for the defense to establish, and that the Government makes out its case when it shows a discrepancy between the actual and the stated weight. On this question, also, no light is furnished by way of decisions. I can only say that on a close reading of the text, I am of the opinion that the proviso is imbedded in the prohibition; that is, that the offense is limited by the proviso. If this reading be correct, then the duty of the Government is to establish the existence of the offense, as limited by the proviso; that is to say, the Government must go further, and show that the deficiencies in question transcended the tolerances granted under the rule. If, by reason of the amorphous character of the rule, this task is extraordinarily difficult, the answer must be that the defendant is not responsible for the language of the statute or the rule.

In reviewing the law, I have not found this case to be modified, distinguished or reversed.

I have heretofore referred to the statutory provisions of New Jersey as being typical, in substance, of the laws of the several states. Prior to 1955, the weights-and-measures officials of the state refused to promulgate any regulations authorizing variations and tolerances for packaged products. However, in a case decided by the Supreme Court of New Jersey[9] in March, 1955, the question was raised as to whether or not the conviction of a defendant could stand where no consideration for variations in weight had been given by the state weights-and-measures officials. In this case the product involved was one-pound prints of butter which, upon being tested, had a variation of one fourth of an ounce and three eighths of an ounce less than the weight marked on the package. After a lengthy review of the constitutionality of the act, the court made this significant statement:

. . . we are convinced that the legislation now in effect requires that the *superintendent first prescribe reasonable variations and thereafter enforce the marking provisions applicable to packaged food* under RS 51:1-29 N. J. S. A. This was not done in the instant matter and the county courts therefore rightly reversed convictions which had been entered in the municipal courts. [Italics supplied.]

The well-reasoned cases which have just been cited illustrate the sound logic underlying the recognition of the facts of life concerning loss of moisture in food products and the resultant variations in weight.

Retailers are often charged under a state statute or city ordinance which, in substance, states that when an article is sold by weight, the seller shall give 16 ounces to the pound. Even though the manufacturer is not charged with violation and even though it might well be

[9] See *State of New Jersey v. Hotel Bar Foods, etc.*, cited at footnote 5.

that at the time of the manufacturer's sale to the retailer there was no violation, the manufacturer is vitally interested in the outcome of the charge against the retailer because he must consider his continuing relationship with his customer. After all, the preparation, distribution and sale of food is one of the most highly competitive businesses in the world. Therefore, as a practical business matter, the manufacturer may assume responsibility for his customer's weight cases, in order to protect the retailer and to retain his good will. Obviously, the manufacturer will not retain his customer if his customer is continually in trouble because of weight problems involved in handling the manufacturer's prepackaged products. The manufacturer is not only vitally interested in having the proper type of law applied, that is, one which permits reasonable tolerances, but he must explain to his customer the difference between selling by weight and by the package, and its effect when selling products subject to natural shrink.

Prepackaged foods are here to stay. The consuming public would be completely unwilling to return to old methods of distribution of food products. Self-service in supermarkets has a wide appeal to the housewife and to the man of the house who not infrequently assumes the responsibility of the family shopping.

Not only have prepackaged foods gained wide acceptance by the consuming public, but the consuming public has derived many benefits from modern, up-to-date methods of merchandising food products. They are confronted with a more attractive display of foods. They are provided with a greater variety of products. The product they buy is of high quality and ready for immediate use or cooking, without any effort or time required in preparation. Most important of all, they receive a product which has not been subjected to intermediate handling by an unknown number of persons, thus eliminating the possibility of contamination through additional handling and exposure.

What does the housewife buy? Does she buy a given amount of weight or does she buy a given value of nutrition? Variations in weight caused by loss of moisture do not affect the nutritional value of food. The nutritional factor in the food will remain constant regardless of the extent of the loss of moisture. For example, the standards of identity for butter call for the product to contain 80 per cent of milk fat. Assuming that one pound of butter complies with the standards and contains exactly 80 per cent of milk fat, said pound of butter

will actually contain 12.8 ounces of fat. If you further assume that the product has been held for a sufficient period of time and the original weight of 16 ounces has been reduced by loss of moisture to 15¾ ounces, an analysis of the butterfat percentage will show the milk fat percentage has risen from 80 per cent to 81.27 per cent. The weight of the fat in ounces, however, remains constant at 12.8. So you see that while the weight of the over-all product may have diminished by one fourth of an ounce through loss of moisture, the food value which the consumer purchases still remains in the product. It is common knowledge that in cooking meats or any other foods which contain moisture, the cooking process will result in a loss of from 35 to 50 per cent of moisture. Therefore, if you were to assume that at the time of the purchase of a ham the weight had diminished by 1 per cent in loss of moisture because of handling, to me it seems rather futile to raise an issue about the 1 per cent loss when it must be realized that (1) the food value is still in the ham and (2) a far greater amount of moisture will be lost during the cooking process before it is ultimately consumed.

There may be some who are of the opinion that it is impossible to determine what constitutes a reasonable variation in moisture and what is good distribution practice. However, if one makes a realistic approach to the facts, this problem disappears. The variation of weight in food products is self-limiting. Have you ever seen a housewife purchase overage marshmallows, bread, sliced bologna or cheese? We all know that as a marshmallow loses moisture, it becomes hard and tough. When an excessive amount of moisture is lost from this product, it becomes unsalable. The same would be true of bread, fresh produce, all varieties of meat, cheese, and a multitude of other products. When any product has lost sufficient moisture to lose its firmness or color or the natural texture of its body, it becomes a product which is undesirable and which customers will not purchase. It is, therefore, to the best self-interest of the manufacturer and the retailer to handle products according to the best methods and distribution practices. A customer will not buy a bad product a second time and if a number of different products which are bad are bought in one retail store, the retailer will have lost a customer. You may rest assured that in 1956 both the manufacturer and the retailer are continually exploring every possible way in which fast distribution can be accomplished. They are constantly introducing new and improved methods designed to

make perishable products reach the ultimate consumer in the best possible condition.

How does the federal weights-and-measures rule affect the administration and enforcement of the law on the part of the public official? I respectfully submit that it makes available to said official the most effective means of protecting the ultimate consumer. He is in the position of being able to handle any given problem on an administrative basis or, if that proves to be insufficient, to refer the matter to the courts in order to obtain the desired result. If an inspector finds a product in retail stores to be at a variance in weight with the marked weight of the package, he may then call in the manufacturer or the retailer to show cause why criminal proceedings should not be instituted. The burden of showing that the variation is reasonable and that the product has been handled in accordance with good distribution practice is then placed on the manufacturer and the retailer. If the manufacturer and the retailer sustain the burden and convince the official that the variation is reasonable and normal under the circumstances, the matter would be concluded at that point. If, however, the manufacturer and the retailer fail to sustain the burden of proof, the official is still in a position to refer the matter to the courts for appropriate action. This method of administration is far more flexible than that in which the only alternative the weights-and-measures official has available is referral of the matter to the courts.

In conclusion, it should be pointed out that the laws of most of the states governing weights of packaged product were enacted prior to the year 1925. At the time of the enactment of said laws, the weighing and packaging of product were practically simultaneous at the time of sale. Modern problems involved with prepackaged foods were virtually nonexistent. In spite of this, however, practically every statute provides that variations and tolerances shall be created. The courts of the State of Texas recognized this problem as early as 1922. The principle has been incorporated into the Federal Food, Drug, and Cosmetic Act, and the regulations of the Food and Drug Administration, and this rule has further been adopted by a substantial number of state and local jurisdictions. I believe that the federal rule most nearly accomplishes the purpose for which net-weight laws are enacted when you consider the necessity of having a law which protects the public, is fair to the manufacturer and provides the public official with an efficient vehicle for law enforcement. **[The End]**

Some Aspects of the Work

OF THE CANADIAN FOOD AND DRUG ADMINISTRATION WITH PARTICULAR REFERENCE TO FIELD SERVICES

By H. E. WOODWARD

With No Canadian Provincial Food-Drug Offices Akin to Those of State Control in the United States, the National Field Service Is of Particular Importance

Organization

The field service of the Canadian Food and Drug Directorate is composed of 26 field offices manned by a staff of some 70 inspectors.

Branch laboratories were established in Halifax, Winnipeg and Vancouver in October, 1913, under the authority of the Adulteration Act 1884, which at that time was administered by the Department of Inland Revenue. The Montreal laboratory was opened in 1920 and the one in Toronto in 1927. By this time the adulteration act had been superseded by the Food and Drugs Act 1920, and was administered by the Department of Health.

These five laboratories later became the regional headquarters for the administration of the act.

The formation of 25 district offices had been authorized in December, 1918. The twenty-sixth, at Windsor, Ontario, was opened in 1951 by the subdivision of the London District. Most of the work of inspection, sampling and testing is carried out in these field offices and laboratories.

In the early days, while district inspectors carried out a few laboratory tests in their own offices, the bulk of the samples taken were sent to the Ottawa headquarters for analysis. Following the establishment of the regional laboratories, this work was transferred to them.

The regional offices, in addition to clerical staffs, are composed of a laboratory and an inspection division, each headed by a superintendent. The whole office is in charge of a regional director, whose

The Writer Is Director, Central Region, the Canadian Food and Drug Directorate

authority stems from that of the director in the Ottawa headquarters. District offices in cities where the regional office is located have up to ten or more inspectors on their staffs, while the remaining offices are manned by one or two men.

Scope of Function

A reorganization of the divisions in 1945, under the present Director, formulated a policy of the self-sufficiency of the regional offices as far as is practical, with the regional directors as deputies of the Director. The limitation here is, of course, the necessity for country-wide uniformity of enforcement. The formulation of basic policy must therefore emanate from Ottawa.

No department of government functions independently of others, and a close liaison with these departments is essential to efficient administration. This is effected to some considerable extent with headquarters offices of the federal government, but with local federal, provincial and municipal offices it can be accomplished more readily by local contact than from Ottawa. As will appear later, this has been amply demonstrated recently in the evaluation of a workable sanitation program. In other than government circles, the regional and district offices have also more immediate and constant contact with many trade and industrial firms, and their associations.

In Canada there are no provincial food and drug offices corresponding to those of state control in the United States. In this respect the duties of the Canadian directorate are more inclusive. The Food and Drugs Act is criminal law, and its provisions are applicable to all foods and drugs sold anywhere in Canada regardless of whether or not they are involved in interprovincial trade.

There is, of course, other legislation concerned in food and drug control, including the Canada Dairy Products Act; the Fruit, Vegetables and Honey Act; the Meat and Canned Foods Act; the Maple Products Industries Act; the Fish Inspection Act; the Proprietary or Patent Medicines Act; and the Opium and Narcotic Drugs Act, as well as legislation at the provincial and municipal levels. Federal food legislation other than the Food and Drugs Act is concerned largely with the establishment of grade standards and inspections relating thereto —a phase of the subject in which the directorate is not involved. In passing, it is of interest to note that firms engaged in interprovincial or export commerce are required to register for inspection under the appropriate federal act.

Provincial and municipal acts and bylaws, where they are not concerned with grading, are more restrictive than the Food and Drugs Act, and there appears to be no conflict of requirements. The public health acts of the provinces deal largely with communicable disease and environmental sanitation and, in the field of food-plant sanitation, are concerned with many matters which are the concern also of the Food and Drug Directorate.

Sanitation

The self-evident importance of control of food and drugs at the production source has not always been clearly recognized by appropriate legislation.

In Canada, until the coming into force of the revised Food and Drugs Act in July, 1954, the conditons which could be considered to render a product adulterated were clearly set out, but it was necessary to be able to prove adulteration by laboratory analysis in order to establish in court a violation of the act. This, as will be appreciated, was sometimes difficult and occasionally impossible of accomplishment. I believe a similar condition existed in the United States until the passing of the 1938 Federal Food, Drug, and Cosmetic Act.

Our present act changed this condition, and now Section 4 states: "No person shall sell an article of food that . . . (2) was manufactured, prepared, preserved, packaged or stored under unsanitary conditions." Also Section 7 states: "No person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions." There are similar sections pertaining to the sale and manufacture of drugs.

There are two important connotations concerned here. The term "sell" is defined to include "sell," "offer for sale," "expose for sale," "have in possession for sale" and "distribute"; "unsanitary conditions" is defined in Section 2(n) as meaning "such conditions or circumstances as might contaminate a food, drug or cosmetic with dirt or filth or render the same injurious to health." It will be appreciated that "might contaminate" is capable of very wide application. The act, therefore, provides for broad coverage in this field.

It may be of interest to note that an inspector is not required to give notice, written or otherwise, of his intention to inspect a plant. He is, however, empowered to enter and perform his duties only at a time which is "reasonable." As this word and its adverbial form occur seven times in Section 21, in which section the powers of the inspectors are set out, it is clear that Parliament intended this virtue to dictate the actions of the food and drug inspectors.

Within the indicated limitation, an inspector may enter a plant; examine and take samples of products; open and examine any pertinent receptacle or package; examine books, documents or other relevant records; and seize and detain any article concerned with food and drug activities. A copy of a record, certified by the inspector to be a true copy, is receivable in evidence and is prima-facie proof of the contents thereof.

Owners or persons in charge of inspected places are required to assist and refrain from obstructing an inspector in the performance of his duties. Where a substance which might be used to adulterate a food or drug is found on the manufacturing premises and in the product, the onus of proving that the food or drug was not adulterated by the addition of such substance lies with the person so accused.

There are two main aspects of factory inspection. One concerns the composition and labeling of the factory products and the other the sanitary conditions pertaining to the plant. Because of the recent passage of enabling legislation, the second of these two phases has received more attention during the last 18 months than have some other aspects of the law.

There are, particularly in Eastern Canada, a large number of plants which manufacture, process and package foods and drugs. For obvious reasons, sanitation is a bigger problem in the food field than

in that of drugs, and we have carried out many inspections in flour mills, cheese factories, poultry and meat canning and packing plants, storage warehouses, etc. This work is planned and executed in the regional offices of the Directorate.

Much has been accomplished in this relatively short time in bringing about improved factory sanitation—so far, fortunately, without much need to resort to prosecution. As might be expected, the plants of the larger "name brand" products are usually well out in front in the matter of possession of satisfactory equipment and in the practice of modern and efficient methods of sanitation. Those of intermediate size in general are good; where improvement is required, management is usually willing to adopt the necessary measures. Many of the smaller plants are in good sanitary condition, but most of the less satisfactory ones are found in this group. Because of the small investment required, real hardships may be involved in making necessary improvements. In this same group also are found most of those plants whose owner's or manager's background of education and experience does not permit him to appreciate the necessity for the adoption of the principles of sanitation. Persuasion in this direction is consequently of no avail.

We have made it a practice, wherever possible, to notify inspectors of other government departments and local health authorities of our plan to inspect plants in a specified district and to invite cooperative inspection where common interests are involved. In general, this plan works out well, and possible friction regarding overlapping jurisdiction is largely avoided.

Under the provincial health acts, the equipment requirements and other sanitary requirements are quite specifically laid down by regulations. There are no corresponding regulations under the Food and Drugs Act, which is therefore not subject to the limitations which specific requirements might impose.

The Directorate feels that work of this type in food and drug plants requires, among other things, a considerable degree of academic knowledge in order that the inspector may talk not only with plant management concerning their problems, but also with the control and research chemists in their fields, and act in an advisory capacity to both. For some years, inspectors who have been added to our staffs are university graduates in a science related to this type of work, and in addition they have received instruction in the form of course work

from specialists in the various fields of interest, on-the-job training with experienced men, frequent regional and local conferences, etc.

Imports

Another matter which is largely the concern of the field services is the examination of import goods from all sources outside of Canada.

The same regulations apply to import goods as apply to products produced in Canada. Under authority of Section 24(1)(d) of the Food and Drugs Act, the Governor in Council has passed a regulation (A.01.042) which provides that a food, drug, cosmetic or device which, if sold in Canada, would constitute a violation of the act or regulations shall not be admitted into the country. However, the following regulation (A.01.043) makes provision for the entry for relabeling or reconditioning of such products as are in violation of the act provided this is completed satisfactorily within a period of three months of the date of the report.

The large and growing number of customs ports of entry, some of which have increased in number of entries manyfold in recent years, presents a volume of work for food and drug inspectors which cannot be handled in any complete way with the available staff, and it is necessary to rely on "spot checking" of many products, with thorough examination of a smaller list, in order to be assured that the public is properly protected from health hazards and reasonably so from major and minor frauds.

This would not be possible without the cooperation of the customs and excise officers of the Department of National Revenue, who are usually willing to put aside for our examination certain types of products from a list prepared for their use. Ports officials, where there is no resident inspector, will either remanifest parcels to the nearest city in which there is a food and drug inspector or notify us by form letter, with which we provide them, when an inspector can arrange to visit the port.

Large shipments of import figs, dates, nuts and other products have in the past been a matter of some concern to us, since examination for filth and infestation involved the obtaining of samples from shiploads or freight carloads which, while of a reasonable size, could nevertheless be taken as being truly representative of the whole. Also, examination technique had to be so standardized that findings would be the same regardless of which laboratory conducted the examination.

This was a large undertaking. In one season over 40,000 figs and dates were individually and carefully microscopically examined in one of our laboratories alone. The Directorate, with assistance from the National Research Council of Canada, finally worked out a very satisfactory minimum-cost two-stage single samplying plan for the classification of good- and bad-quality lots, with specified risks of error (Dunnett and Hopkins, *Two-Stage Acceptance Sampling by Attributes* (American Society for Testing Materials 1951 Special Technical Publication No. 114)).

Advertising

Among the difficult problems to handle are some concerned with advertising. An "advertisement," according to Section 2(a) of the Food and Drugs Act, includes any representation by any means whatever for the purpose of promoting directly or indirectly the sale or disposal of any food, drug, cosmetic or device. Oral, as well as written, advertising is therefore included, as is also the labeling of packaged goods.

Difficulties in the field offices are not those of deciding what constitutes erroneous or misleading advertising. As pointed out by our Director in a recent article (10 FOOD DRUG COSMETIC LAW JOURNAL 753 (November, 1955)), the principles on which these are judged are discussed in a booklet entitled *Guide for Manufacturers and Advertisers*. The difficulties lie, rather, in the large quantities of material to be examined.

In giving their due priority to all types of work, much advertising —particularly in the field of labeling—must necessarily pass without scrutiny by our staffs. However, much of minor significance is forced upon our attention by competitive firms and others, and must be given consideration. This, in fairness to all involved, requires a review of all similar products to be found on the open market and those entering from foreign countries.

In this latter respect, perhaps, we can look forward to international agreement on some aspects of labeling as a development of the present interest in uniform standards concerning colors, chemical additives, pesticides, etc. Such agreements, in addition to the more fundamental advantages, facilitate trade and lighten the duties of enforcement officers. Particularly, perhaps, with the United States, some agreement might be possible on the location, conspicuousness, wording, etc., of mandatory statements on labels. On vitamin preparations, uni-

formity regarding units of vitamin content, minimum and maximum quantities which may be shown, etc., would eliminate much work in this considerable field.

Publicity

The obligation to the public to publicize the work of the Department is well recognized, as is also its value in our development. Budgetary considerations, however, impose strict limitations on what can be accomplished.

Because of our wider and more immediate contact with the public, the regional and district offices are logical centers for the dissemination of information. Our officers and inspection staffs can effect a wide distribution of descriptive literature. Talks to university and school groups, and social, professional and trade organizations are usually received with enthusiasm. Displays at national and provincial exhibitions and fairs are ideal means of explaining how, at a very low per-capita cost, the government is protecting the health and pocketbooks of the people. Radio, television and newspaper coverage have added their share to extending public appreciation of the activities of the Food and Drug Directorate. **[The End]**

REPORTS TO THE READER—Continued from page 500

He joined the food and drug staff of Canada's Department of National Health and Welfare after his graduation, and studied toward an M. S. degree, which he secured in 1929. On the death of the Winnipeg chief in 1935, he was promoted to his present position with the department—regional director.

Arthur C. O'Meara, assistant general counsel for Swift & Company, was born in Chicago. He holds college and law school degrees from the University of Chicago, and was admitted to practice in 1933. Until 1934 he was engaged in private practice; in that year, he went to the law department of Swift & Company. He was head of its labor division from 1945 to 1950, and served as its general attorney from 1951 to February 1, 1956, when he assumed his present post.

H. E. Woodward has been regional director of the Central Region of the Canadian Food and Drug Directorate since 1949. Prior to that time, he was superintendent of the Toronto laboratories for eight years. Before joining the directorate, he was an assistant professor of chemistry at the University of Pittsburgh, where he had taken his Ph. D. degree.

In the Food and Drug Administration

Monthly Report, Issued September 27.—Six hundred tons of food unfit

for consumption were seized in 43 federal court actions during August, the Food and Drug Administration reported on September 27. An additional 77 tons were voluntarily destroyed or diverted by the owners to nonfood use.

Sixty-eight tons were contaminated by deleterious chemicals. Included in such foods were ice-cream cones containing boric acid, wheat treated with a mercurial compound for seed use, an imitation vanilla flavoring containing coumarin, and frozen spinach with excess DDT residues.

Other shipments were seized for filth contamination—532 tons. Among them were five carloads of bulk wheat. These were the first actions since higher standards of cleaniness for bulk wheat went into effect on July 1. The Administration stated that it was possible to raise the standards because there has been a progressive improvement in the sanitary handling of wheat. The new standards will promote increasing cleanliness in grain intended for food use.

One seizure was made to stop deception of consumers. A shipment was labeled "corn and olive oil," but it contained cottonseed oil.

Four lots of drugs were seized for adulteration or misbranding. One lot was seized because it was a new drug, the safety of which had not been cleared.

Safety Controls—Insecticide Residues.—The Food and Drug Administration announced on October 23 that new scientific evidence requires it to tighten safety controls over residues of organic phosphate insecticides used on food crops. Additional scientific testing, according to officials, will be necessary in order to obtain official "tolerances" for sprays and dusts containing these chemicals.

Commissioner of Food and Drugs George P. Larrick explained that it has been found essential to test such insecticides for "potentiation." Potentiation means here an increase of toxicity which has been found to occur when some of the compounds are used together. The basis for the action is the discovery by FDA scientists that some organic phosphate insecticides may greatly increase the toxicity of others when they are fed to animals simultaneously. For instance: It takes 50 parts per million of EPN in the diet of dogs to produce a noticeable effect. It takes 250 parts per million of malathion to produce a similar effect. When only 20 parts per million of EPN and 100 parts per million of malathion are fed at the same time, the combination is quite toxic to the dog.

Scientists had for some time suspected that some organic phosphate compounds might potentiate the toxicity of others. It was proved only recently by FDA pharmacologists experimenting in Washington that two of the chemicals actually do behave this way.

Both of the mentioned compounds are used on food crops, and slight residues are permitted on certain commodities when marketed. However, the official tolerances do not permit them to be present simultaneously in possibly toxic concentrations. Commissioner Larrick stated:

"The FDA has been careful in establishing tolerances. There is no indication that the tolerances now in effect for any of the organic phosphates constitute any hazard to the public health. But to be sure that we continue to safeguard the consumer adequately, we are going to require more evidence of safety in dealing with this type of compound in the future."

The nature of the additional evidence to be required was outlined in a policy statement published in *Federal Register*—also on October 23. The statement referred to the new discoveries in FDA's laboratories, saying:

"Therefore in considering a petition for a tolerance or tolerances for an

organic phosphate pesticide, the Food and Drug Administration will require experimental evidence showing the toxicity of the compound when fed to test animals with each of the other organic phosphate pesticides which has a tolerance at that time. This requirement will be relaxed if additional scientific evidence shows it can be done without hazard to the public health."

Official tolerances are presently in effect for five organic phosphate pesticides: parathion, methyl parathion, malathion, EPN and Systox. The new requirements will make it harder for pesticide chemical manufacturers to get new tolerances. A firm that desires a tolerance for a new compound in the group will have to determine its toxicity alone and also in combination with each of the five other organic phosphates already having tolerances.

Arnold J. Lehman, M. D., Chief of FDA's Division of Pharmacology, has noted that such testing is necessary because no one knows the mechanism by which one organic phosphate potentiates the toxicity of another. However, he stated:

"As soon as someone works out the mechanism of the potentiation, it may be possible to determine the safety of a new compound with less research than is needed today; we are having to ask for more data now because the fundamental science of this phenomenon (potentiation) is not understood. When we understand the fundamental science, the scope of the problem will become apparent. This may permit a distinct shortening of the research required in this field."

Commissioner Larrick praised Dr. Lehman and the scientists who discovered these new facts. He said:

"It is gratifying that our scientists were able to make this discovery before more tolerances had been established. Their foresight in this field is an example of the type of research that will become increasingly important in our work of protecting the public."

Pilot Reporting System on Effects of Drugs.—Prompt reporting of unusual or adverse reactions to drugs is the objective of a new joint study being carried on by 11 leading hospitals. The pilot reporting system, sponsored by the Food and Drug Administration—and announced by it on October 17—is being developed with the collaboration of the American Association of Medical Record Librarians, the American Society of Hospital Pharmacists, the American Medical Association and the American Hospital Association.

The Administration stated that such a reporting system has been taken in order to obtain information regarding drug effects which may appear in some patients when the drugs are administered to large numbers of people. This problem has been magnified by the increasing number of potent new drugs. Even the most extensive clinical studies cannot forecast all types of reactions which may develop throughout the population. Hospitals provide an ideal situation for observing effects and obtaining essential information not available from other sources. The joint study is being undertaken in the interest of public health, better patient care and the furtherance of the objectives of the Federal Food, Drug, and Cosmetic Act to insure the safe use of drugs.

Participating hospitals include: George Washington University Hospital, Washington, D. C.; Grace Hospital, Detroit, Michigan; Hartford Hospital, Hartford, Connecticut; Oakwood Hospital, Dearborn, Michigan; Lakewood Hospital, Lakewood, Ohio; Medical College of Virginia Hospital, Richmond, Virginia; St. Joseph's Hospital, Providence, Rhode Island; United States Naval Hospital, Bethesda, Maryland; United States Public Health Service Hospital, Baltimore, Maryland; Walter Reed Army Hospital, Washington, D. C.; and Western Pennsylvania Hospital, Pittsburgh, Pennsylvania.

Meetings of Food and Drug Men

University of Tennessee.—The University of Tennessee College of Law and the Knoxville Bar Association are presenting a product-liability institute at the college, at Knoxville, on November 2. There is no registration fee, and the meeting is open to all attorneys and insurance-company representatives. Scheduled guest speakers include: William J. Weinstein, member of the Detroit bar; Arnold Elkin and William J. Condon, members of the New York bar; and William D. Buchanan, member of the Grand Rapids bar.

Association of Official Agricultural Chemists, Inc.—The seventieth annual meeting of the Association of Official Agricultural Chemists was held October 15-17 at the Shoreham Hotel, in Washington, D. C. The meeting emphasized the application of modern methods of analysis to the enforcement of the Nation's laws regulating composition and labeling of foods, drugs, cosmetics, animal feeds, fertilizers and pesticides. Held in cooperation with the Food and Drug Administration, Department of Health, Education, and Welfare, and the Meat Inspection Branch, Department of Agriculture, the association's meeting commemorated the golden anniversary of the passage of the 1906 Federal Food and Drugs Act. It also honored Harvey W. Wiley, the "father" of the Act. Dr. Wiley was also one of the founders of the association.

On the first night of the meeting, Kenneth D. Jacob, president of the association, announced the establishment of the Harvey W. Wiley award for analytical methods. Dr. Wiley's son, John Preston Wiley, and his granddaughter, Adelaide Wiley, thanked the association on behalf of the family. Mrs. Harvey W. Wiley, widow of the pure-food crusader, listened to the program from her home, where she is recovering from an illness.

Mr. Jacob announced that the annual award—carrying a cash prize of $500—will be presented to the scientist or group of scientists who make an outstanding contribution to development of methods of analysis of foods, cosmetics, drugs, feeds, fertilizers, pesticides and soil, or for methods in general analytical chemistry. These are the fields of interest of the Association of Official Agricultural Chemists, encompassed by its publication *Official Methods of Analysis*, primary laboratory manual of regulatory chemists and research workers in agriculture.

The first award will be made at the seventy-first annual meeting of the association next October. All scientists are eligible for the award.

In announcing it, Mr. Jacob said:

"The year 1906 marked the enactment of a Federal law which was destined to have a far-reaching influence on the daily lives of each and every one of us. It is fitting, therefore, that the fiftieth anniversary of the passage of this law is being celebrated this year throughout the Nation and that homage is being paid to the man who, above all others, worked so long and so well in its behalf.

"To the American public, Dr. Harvey Washington Wiley will always be known, and rightly so, as the 'Father of the Pure Food and Drug Law'. In the annals of the Association of Official Agricultural Chemists his name will be inscribed forever as the one who contributed in unparalleled degree to the welfare of the Association and to the progress of agricultural chemistry in the United States. His association with the A. O. A. C. extended over a period of nearly 50 years, as one of its founders in 1884, president in 1886, secretary from 1889 to 1912, and honorary president until his death in 1930.

"In further recognition of his service to the Association and to the Nation, it gives me great pleasure to announce the establishment by the Association of the Harvey W. Wiley Award for Development of Analytical Methods. This annual award, in the sum of $500, will be given to the scientist or group of scientists judged to have made an outstanding contribution to the development of methods of analysis in the fields of the Association's interest."

Principal speaker at the banquet meeting was Dr. Frederick L. Hovde, president of Purdue University, where Dr. Wiley was a professor of chemistry before he entered the federal service and began his famous crusade.

At a general session of the meeting, R. E. Proctor, head of the food-technology department of the Massachusetts Institute of Technology, discussed radiation problems of food and drugs. Dr. E. P. Laug, of FDA, presented a recently declassified report on his civil-defense project to determine the effect of nuclear explosions on foods which were exposed during "Operation Teapot" in the spring of 1955. The application of gas chromatography—a technique less than five years old—to food analysis was presented by R. D. Stanley and F. H. Vannier of the United States Department of Agriculture, Pasadena, California.

An entire day's session of the meeting was devoted to a symposium on methods of analysis for detection of minute amounts of pesticide residues in foods, resulting from the application of protective sprays during the growing of crops. Papers were presented by S. A. Shrader and D. A. Mapes, of Dow Chemical Company; C. L. Dunning, of Diamond Alkali Company; H. L. Williams and J. P. Sweeney, of the United States Department of Agriculture; Constance Anglin and J. P. Mahon, of the Canadian Food and Drug Division; and L. L. Ramsey, H. W. Conroy, V. E. Munsey and G. E. Keppel, and others, from the Food and Drug Administration.

Results of the application of present-day methods of analysis to detect water in milk were discussed by Dr. A. H. Robertson, of New York, who has completed a two-year survey of the constants of pure milk. Department of Agriculture scientists B. A. Brice, A. Turner, Jr., and J. W. White, Jr., of Philadelphia, discussed the use of color standards for grading honey. Morris D. Finkner, of Beltsville, Maryland, spoke on the application of statistics to methods of analysis, and Marilyn J. MacArthur and E. W. Toepler, both of Beltsville, discussed the determination of vitamin B_6. Dr. B. E. Oser, of Food Research Laboratories, Long Island City, New York, outlined the work of the International Vitamin Commission on Vitamin A collaborating studies.

In the field of methods for the determination of the important fertilizer components—nitrogen, phosphorus and potassium—were the offerings of the following speakers: J. A. Brabson and W. D. Wilhide, of the Tennessee Valley Authority, presenting an automatic titration method for phosphorus; C. W. Gehrke, of the University of Missouri, presenting a flame photometer method for potassium; and P. A. Greene, of Allied Chemical and Dye Corporation, discussing sampling of pressure fertilizer solutions.

The annual address of the association's president was on the subject "Twelve Decades of Commercial Fertilizers." Mr. Jacob is with the United States Department of Agriculture, at Beltsville.

Food and Drug Administration.—The fourth annual symposium on antibiotics, sponsored by the Food and Drug Administration in collaboration with the journals *Antibiotics and Chemotherapy* and *Antibiotic Medicine and Clinical Therapy*, was held at the Willard Hotel, Washington, D. C., October 17-19. A total of 156 papers was scheduled for the program, and nine foreign countries sent representatives.

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